UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

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Tammy Smith, Andy Green Jr., Golbenaz Bakhtiar, Richard Obrien, Virginia Aragon, Jeffrey Pisano, Angel Cordero, Gustavo Velasquez, Joshua Winans, Ricardo Moròn, Roy Armstrong, Sonia Diaz, Kathy Jeffries, Earlene Green, Charles Longfield, Janet Asbury, Randy Jones, Alberta Griffin, Ida Adams, Jerry Hunt, Lakisha Wilson, Donald Northrup, John Scholl, Beverly Crosby, John Rachal, Gaylord Stauffer, Benny Fazio, Mary McCullen, Dennis Robbins, Chris Troyan, Michael Galloway, Nicholas Hazlett, Gloria Colon, Dale Hunter, Kenneth Hix, Sylvia Yoshida, Ronda Lockett, Marianella Villanueva, Dan Zhovtis, Jonathan Ferguson, Steve Fischer, and Wendy Quezaire, on behalf of themselves and all other similarly situated,

Plaintiffs,

v.

Pfizer Inc.,

Defendant.

CASE NO: 22-cv-00746
JURY TRIAL DEMANDED

CONSOLIDATED
ECONOMIC LOSS CLASS ACTION COMPLAINT
AGAINST DEFENDANT PFIZER, INC.

Plaintiffs file this Master Economic Loss Class Action Complaint ("ELC") on behalf of themselves and all others similarly situated against Defendant Pfizer, Inc. ("Pfizer"), and seek damages and equitable relief to remedy the economic losses resulting from Pfizer's design, manufacture, marketing, packaging, labeling, handling, distribution, storage, and/or sale of over-the-counter ("OTC") ranitidine-containing medications, sold under the brand-name Zantac.[1] Plaintiffs' allegations are based upon personal knowledge as to Plaintiffs' own conduct, investigation of counsel based on publicly-available information, and the discovery conducted to date.

I. INTRODUCTION

Zantac is the branded name for ranitidine, a drug that was touted and sold for nearly four decades as a safe and effective heartburn and indigestion drug. Zantac and other Ranitidine-Containing Products were among the most popular heartburn drugs purchased by U.S. consumers. Indeed, Zantac was the first-ever "blockbuster" drug to reach $1 billion in sales.

This unprecedented sales volume, and the additional billions of dollars generated through sales of Zantac and other Ranitidine-Containing Products for nearly 40 years, were made possible because of a deceptive and unlawful scheme by Pfizer to defraud consumers regarding the purported safety of Zantac and other Ranitidine-Containing Products, and by concealing from consumers the known dangers and risks associated with use of this drug.

But, recent scientific studies confirmed what Pfizer knew or should have known all along: ranitidine transforms over time and under natural conditions into high levels of N-Nitrosodimethylamine ("NDMA"), a carcinogen that is potent and dangerous. The U.S. Food &

[1] All prescription and OTC ranitidine-containing medications, are referred to collectively as "Ranitidine-Containing Products" or "Zantac".

Drug Administration ("FDA") recognizes NDMA as "a probable human carcinogen"[2] and the World Health Organization ("WHO") has described it as "clearly carcinogenic."[3] Its only use is to induce cancerous tumors in animals in laboratory research and experiments; it has no medicinal purpose.

In 2019, an analytical pharmacy ran tests on Zantac and discovered the link between ranitidine and NDMA and that ranitidine itself is unstable and can break down into NDMA, particularly in the environment of the stomach. On September 13, 2019, the analytical pharmacy filed a citizen petition asking the FDA to recall all products that contain ranitidine. In early October 2019, the FDA ordered testing on Zantac and other Ranitidine-Containing Products and specified the protocols for such testing. Within days of the FDA's announcement, certain manufacturers recalled Zantac and Ranitidine-Containing Products in the United States and internationally. On November 1, 2019, the FDA announced that its recent testing showed "unacceptable levels" of NDMA in Zantac and other Ranitidine-Containing Products, and requested that all manufacturers recall Zantac and other Ranitidine-Containing Products. Ultimately, on April 1, 2020, the FDA called for a withdrawal of Zantac and all other Ranitidine-Containing Products in the United States, citing unacceptable levels of NDMA in those drugs.

Over the nearly 40 years that Zantac and other Ranitidine-Containing Products were marketed and touted as safe and effective, Pfizer uniformly deceived millions of U.S. consumers into purchasing a defective, misbranded, adulterated, and harmful drug. Pfizer engaged in a

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[2] U.S. Food & Drug Admin., *FDA Requests Removal of All Ranitidine Products (Zantac) from the Market* (Apr. 01, 2020), https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market.

[3] R.G. Liteplo *et al*., *Concise International Chemical Assessment Document 38: N-Nitrosodimethylamine*, at 4, World Health Organization (2002), https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf.

national, pervasive campaign to conceal the inherent dangers and risks associated with ranitidine use and to mislead consumers into believing that Zantac and other Ranitidine-Containing Products were safe for human consumption. Through product labels and packaging; print, television, radio, and online advertising; Internet websites; and social media, Pfizer uniformly represented that Zantac and other Ranitidine-Containing Products were safe, *e.g.*, so safe that they could be used frequently, for chronic conditions, and for fast relief with nitrite- and nitrate-rich foods (*i.e.* foods that induce heartburn).

These representations were false, deceptive, and misleading when made, and they omitted material facts known to Pfizer regarding the true risks of Zantac and other Ranitidine-Containing Products. Pfizer knew or should have known that ranitidine is an unstable molecule that breaks down under normal conditions into dangerous NDMA, and that this breakdown process is made worse when Zantac and/or other Ranitidine-Containing Products are used in the manner directed or when exposed to routine heat or humidity.

These material facts were known to, or should have been known by Pfizer, which was duty-bound to investigate the potential dangers and risks associated with Zantac and other Ranitidine-Containing Products to ensure that its drug was safe for human consumption.

Despite Pfizer's knowledge of, or duty to know, these material facts, Pfizer did not disclose that Zantac and other Ranitidine-Containing Products were unsafe; that the ranitidine molecule breaks down into carcinogenic NDMA at levels that exceed the maximum daily limit; that Zantac and other Ranitidine-Containing Products should not be used for long-term periods; or that Zantac and other Ranitidine-Containing Products should not be consumed with nitrite- and nitrate-rich foods.

As a direct and proximate result of Pfizer's actions and omissions, Plaintiffs and the Classes suffered economic losses through their purchase of a drug that was unsafe at the point of sale. Hence, Plaintiffs and the Classes suffered economic losses.

Pfizer violated Federal and/or State laws and common law by designing, manufacturing, distributing, packaging, labeling, marketing, and/or selling Zantac and other Ranitidine-Containing Products without adequate testing or labels and warnings; by failing to ensure the proper conditions for the manufacture, transportation, handling, and storage of Zantac and other Ranitidine-Containing Products; and by misrepresenting and/or not disclosing material facts regarding the safety of Zantac and other Ranitidine-Containing Products and the dangers and risks associated with their intended use. Plaintiffs and the Classes seek redress to compensate for their economic losses and to deter the type of misconduct that caused the economic losses they sustained.

This ELC is drafted and organized based on the MDL Court's Orders.[4] Plaintiffs, on behalf of their respective State Classes, then assert separate state law claims against Pzier, under the laws of the state in which each Plaintiff resided at the time of purchase, for violations of state consumer protection laws, breach of implied warranties, and unjust enrichment. Plaintiffs' state law claims are organized by the state in which each Plaintiff purchased Zantac, and against OTC Manufacturers Pfizer for knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for OTC Zantac including by: (i) omitting that it was inherently defective, unreasonably dangerous, not fit to be used for its intended purpose, contained elevated levels of NDMA that rendered it unsafe and unfit for human consumption, and/or caused

[4] *See* Order Requiring Amended Master Pleadings [DE 3751] and Pretrial Order 62 [DE 3083] entered in *In Re: Zantac (Ranitidine) Products Liability Litigation*, MDL No. 2924 (S.D. Fla. Case No. 9:20-md-02924-RLR).

cancer; (ii) printing expiration dates on its labels that exceeded the time period during which the product remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed; and (iii) packaging quantities of tablets in bottles greater than could be used completely and stored properly by the expiration date, particularly when the expiration date on the label was extended beyond a safe and appropriate date.

II. PARTIES

A. Defendant Pfizer

1. Pfizer is an entity that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold prescription and/or OTC Zantac.

Pfizer

2. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017. Defendant Pfizer is a citizen of Delaware and New York.

3. Defendant Pfizer is a manufacturer, distributor, and seller of brand OTC Zantac.

B. Non-Party Brand Manufacturers[5]

Boehringer Ingelheim (BI)[6]

4. Non-Parties Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation are U.S.-based corporations that are direct or indirect subsidiaries or affiliates of Non-Party Boehringer Ingelheim International GmbH,

[5] The below listed entities are not parties to this litigation, but are, like Pfizer, manufacturers of name-brand Zantac and defendants in the MDL. Collectively with Pfizer, they shall be referred to as "Brand Manufacturers."

[6] Defendant Boehringer Ingelheim also manufactured generic ranitidine under ANDA 074662, as well as through its former subsidiary Ben Venue Laboratories Inc. d/b/a Bedford Laboratories (ANDA 074764). Ben Venue Laboratories Inc. is no longer in operation.

a German limited liability company. Non-Party Boehringer Ingelheim Promeco, S.A. de C.V. is a Mexican corporation that is a direct or indirect subsiary or affiliate of Non-Party Boehringer Ingelheim International GmbH. Collectively, all of these entities shall be referred to as "Boehringer Ingelheim" or "BI."

5. Non-Party BI was a manufacturer, distributor, and seller of brand OTC Zantac.

GlaxoSmithKline (GSK)

6. Non-Parties GlaxoSmithKline LLC are U.S.-based corporations that are direct or indirect subsidiaries of Defendant GlaxoSmithKline plc. Collectively, all of these entities shall be referred to as "GSK."

7. GSK is a manufacturer, distributor, and seller of brand prescription and OTC Zantac.

Sanofi

8. Non-Parties Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., Patheon Manufacturing Services LLC, snd Chattem, Inc. are U.S.-based companies that are direct or indirect subsidiairies or affiliates of

9. Non-Party Sanofi SA, a French corporation.

10. Non-Parties Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Chattem, Inc., Pantheon, andSanofi SA are referred to collectively as "Sanofi."

11. Non-Party Sanofi was a manufacturer, distributor, and seller of brand OTC Zantac.

C. Plaintiffs

12. The following Plaintiffs bring claims against the corresponding Defendant as set forth below.

Alaska

13. Plaintiff Tammy Smith (for the purpose of this paragraph, "Plaintiff") is a citizen of Alaska. Plaintiff purchased Ranitidine-Containing Products in Colorado from approximately 1991 to 1993; in Arizona from approximately 1994 to 1995; in Texas from approximately 1995 to 1996; in Louisiana from approximately 1996 to 1997; in Missouri from approximately 1993 to 1994 and 1997-1998; and in Alaska from approximately 1998 to 1999 and 2002 to 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included the following: (a) prescription Zantac tablets and capsules, from approximately 1991 to 1993 in Colorado, manufactured by GSK; (b) prescription Zantac tablets and capsules, from approximately 1993 to 1994 in Missouri, manufactured by GSK; (c) prescription Zantac tablets and capsules, from approximately 1994 to 1995 in Arizona, manufactured by GSK; (d) prescription Zantac tablets and capsules, from approximately 1990 to 1991 and 1995 to 1996 in Texas, manufactured by GSK; (e) prescription Zantac tablets and capsules, from approximately 1996 to 1997 in Louisiana, manufactured by GSK; (f) prescription Zantac tablets and capsules, in approximately 1999 in Alaska, manufactured by GSK; (i) OTC 75 mg Zantac tablets and capsules, in approximately 1996 in Texas, manufactured by GSK and Pfizer; (j) OTC 75 mg Zantac tablets and capsules, from approximately 1996 to 1997 in Louisiana, manufactured by GSK and Pfizer; and (k) OTC 75 mg Zantac tablets and capsules, from approximately 1997 to 1998 in Missouri, manufactured by GSK and Pfizer. For the purposes of this Complaint, Pfizer is the "Defendant" with respect to Plaintiff's purchases made in Texas while a citizen of Texas; Pfizer is the "Defendant" with respect to Plaintiff's purchases made in Louisiana while a citizen of Louisiana; and Pfizer is the "Defendant" with respect to Plaintiff's purchases made in Missouri while a citizen of Missouri. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-

Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Arkansas

14. Plaintiff Andy Green Jr. (for the purpose of this paragraph, "Plaintiff") is a citizen of Arkansas. Plaintiff purchased Ranitidine-Containing Products in Arkansas and Tennessee from approximately 1983 to 2019. The Ranitidine-Containing Products purchased byPlaintiff that are subject to the Complaint specifically included: (a) prescription Zantac tablets and capsules purchased in Arkansas, from approximately 1983 to 1997, manufactured by GSK, and in Tennessee, from approximately 1987 to 1988, manufactured by GSK; and (b) OTC Zantac tablets and capsules purchased in Arkansas, from approximately 1996 to 2019, manufactured by GSK, Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" with respect to Plaintiff's claims for Plaintiff's purchases in Arkansas while a citizen of Arkansas. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

California

15. Plaintiff Golbenaz Bakhtiar (for the purpose of this paragraph, "Plaintiff") is a citizen of California. Plaintiff purchased Ranitidine-Containing Products in California from approximately 2000 to December 2019. The Ranitidine-Containing Products purchased byPlaintiff that are subject to the Complaint specifically included: (a) OTC Zantac tablets and capsules from approximately 2000 to 2019, manufactured by Pfizer, BI, and Sanofi; and (b) prescription Zantac tablets and capsules beginning in approximately 2000, manufactured by GSK. For the purposes of

this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct

16. Plaintiff Richard Obrien (for the purpose of this paragraph, "Plaintiff") is a citizen of California. Plaintiff purchased Ranitidine-Containing Products in California from approximately 1998 to November 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC Zantac tablets and capsules, from approximately 1998 to 2019, manufactured by GSK, Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

17. Plaintiff Virginia Aragon (for the purpose of this paragraph, "Plaintiff") is a citizen of California. Plaintiff purchased Ranitidine-Containing Products in California from approximately 2006 to 2020. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC Zantac tablets and capsules, from approximately 2006 to 2020, manufactured by Pfizer, BI, and Sanofi. Thus, Pfizer is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore,

were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Colorado

18. Plaintiff Jeffrey Pisano (for the purpose of this paragraph, "Plaintiff") is a citizen of Colorado. Plaintiff purchased Ranitidine-Containing Products in Colorado from approximately 1998 to February 2020. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) OTC Zantac tablets and capsules from approximately 1998 to 2020, manufactured by GSK, Pfizer, BI, and Sanofi; and (b) prescription 150 mg Zantac tablets and capsules, from approximately 1998 to 2003, manufactured by GSK. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Connecticut

19. Plaintiff Angel Cordero (for the purpose of this paragraph, "Plaintiff") is a citizen of Connecticut. Plaintiff purchased Ranitidine-Containing Products in Connecticut from approximately 2005 to 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC Zantac tablets and capsules, from approximately 2005 to 2019, manufactured by Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were

worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Florida

20. Plaintiff Gustavo Velasquez (for the purpose of this paragraph, "Plaintiff") is a citizen of Florida. Plaintiff purchased Ranitidine-Containing Products in Florida from approximately 2000 to February 2020. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC 75 mg and 150 mg Zantac tablets and capsules, from approximately 2000 to 2020, manufactured by Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims.. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

21. Plaintiff Joshua Winans (for the purpose of this paragraph, "Plaintiff") is a citizen of Florida. Plaintiff purchased Ranitidine-Containing Products in Florida from approximately 2000 to 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC 75 and 150 mg Zantac tablets and capsules, from approximately 2000 to 2019, manufactured by Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

22. Plaintiff Ricardo Moròn (for the purpose of this paragraph, "Plaintiff") is a citizen of Florida. Plaintiff purchased Ranitidine-Containing Products in Florida from approximately 1995 to 2020. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC Zantac tablets and capsules from approximately 1996 to 2020, manufactured by GSK, Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

23. Plaintiff Roy Armstrong (for the purpose of this paragraph, "Plaintiff") is a citizen of Florida. Plaintiff purchased Ranitidine-Containing Products in Minnesota from approximately 2004 to 2008; in Georgia from approximately 2008 to 2012; in Alaska in approximately 2011; in New York from approximately 2012 to 2013; in Florida from approximately 2012 to 2017; and in Michigan from approximately 2017 to 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) OTC Zantac tablets and capsules, from approximately 2005 to 2008 in Minnesota, manufactured by Pfizer and BI; (b) OTC extra strength Zantac tablets and capsules, from approximately 2008 to 2011 in Georgia, manufactured by BI; (c) OTC Zantac tablets and capsules, in or around 2011 in Alaska, manufactured by BI; (d) OTC Zantac tablets and capsules, from approximately 2012 to 2013 in New York, manufactured by BI; (e) OTC Zantac tablets and capsules, from approximately 2013 to 2017 in Florida, manufactured by BI and Sanofi; and (f) OTC Zantac tablets and capsules, from approximately 2017 to 2019 in Michigan, manufactured by Sanofi. For the purposes of this

Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in Minnesota while a citizen of Minnesota. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

24. Plaintiff Sonia Diaz (for the purpose of this paragraph, "Plaintiff") is a citizen of Florida. Plaintiff purchased Ranitidine-Containing Products in Florida, from approximately 2017 to 2020, and in Puerto Rico from approximately 2004 to 2017. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) OTC Zantac tablets and capsules, from approximately 2004 to 2017 in Puerto Rico, manufactured by Pfizer and BI; and (b) OTC Zantac tablets and capsules, from approximately 2017 to 2020 in Florida, manufactured by Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims for Plaintiff's purchases in Puerto Rico, while a citizen of Puerto Rico. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Georgia

25. Plaintiff Kathy Jeffries (for the purpose of this paragraph, "Plaintiff") is a citizen of Georgia. Plaintiff purchased Ranitidine-Containing Products in Florida from approximately 1998 to 2002, and in Georgia from approximately 2002 to 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) OTC Zantac tablets and capsules, from approximately 1998 to 2002 in Florida, manufactured by Pfizer;

(b) OTC Zantac tablets and capsules, from approximately 2002 to 2019 in Georgia, manufactured by Pfizer, BI, and Sanofi; (c) prescription Zantac tablets and capsules, beginning in approximately 1998 in Florida, manufactured by GSK; and (d) prescription Zantac tablets and capsules, beginning in approximately 2002 in Georgia, manufactured by GSK. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in Florida, while a citizen of Florida. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

26. Plaintiff Earlene Green (for the purpose of this paragraph, "Plaintiff") is a citizen of Georgia. Plaintiff purchased Ranitidine-Containing Products in Washington that are subject to the Complaint specifically included OTC Zantac tablets and capsules, from approximately 1996 to 2011, manufactured by GSK, Pfizer, and BI. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in Washington, while a citizen of Washington, unless otherwise specified. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

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Iowa

28. Plaintiff Charles Longfield (for the purpose of this paragraph, "Plaintiff") is a citizen of Nebraska. Plaintiff purchased Ranitidine-Containing Products in Maryland in

approximately 1996; in Wyoming from approximately 1997 to 2010; in Maryland from approximately 2011; and in Iowa from approximately 2012 to 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) OTC Zantac tablets and capsules, in approximately 1996 in Maryland, manufactured by GSK and Pfizer; (b) OTC Zantac tablets and capsules, from approximately 1997 to 2010 in Wyoming, manufactured by GSK, Pfizer, and BI; (c) OTC Zantac tablets and capsules, in or about 2011 in Maryland, manufactured by BI; and (d) OTC Zantac tablets and capsules, from approximately 2012 to 2019 in Iowa, manufactured by BI and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in Maryland, while a citizen of Maryland; and Pfizer is the "Defendant" with respect to Plaintiff's purchases made in Wyoming, while a citizen of Wyoming. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Kentucky

29. Plaintiff Janet Asbury (for the purpose of this paragraph, "Plaintiff") is a citizen of Kentucky. Plaintiff purchased Ranitidine-Containing Products in Kentucky from approximately 2003 to 2013. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC Zantac tablets and capsules, from approximately 2003 to 2013, manufactured by Pfizer and BI. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of

purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Louisiana

30. Plaintiff Randy Jones (for the purpose of this paragraph, "Plaintiff") is a citizen of Louisiana. Plaintiff purchased Ranitidine-Containing Products in Louisiana from approximately 1995 to 2020. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) prescription 150 mg Zantac tablets and capsules, beginning in approximately 1995 manufactured by GSK); and (b) OTC Zantac tablets and capsules, from approximately 1996 to 1997 and 2018 to 2020, manufactured by Sanofi, GSK, and Pfizer. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Maryland

31. Plaintiff Alberta Griffin (for the purpose of this paragraph, "Plaintiff") is a citizen of Maryland. Plaintiff purchased Ranitidine-Containing Products in Maryland from approximately 2000 to 2020. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) prescription Zantac tablets and capsules, beginning in approximately 2000, manufactured by GSK; and (b) OTC Zantac tablets and capsules, from approximately 2000 to 2020, manufactured by Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and,

therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

32. Plaintiff Ida Adams (for the purpose of this paragraph, "Plaintiff") is a citizen of Maryland. Plaintiff purchased Ranitidine-Containing Products in West Virginia from approximately 2000 to 2005, and 2012, and in Maryland from approximately 2005 to 2017. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) OTC Zantac tablets and capsules, from approximately 2005 to 2017 in Maryland, manufactured by Pfizer, BI and Sanofi; and (b) OTC Zantac tablets and capsules, from approximately 2000 to 2005, and 2010 to 2012, in West Virginia, manufactured by Pfizer and BI. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in Maryland while a citizen of Maryland; and Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in West Virginia while a citizen of West Virginia. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Michigan

33. Plaintiff Jerry Hunt (for the purpose of this paragraph, "Plaintiff") is a citizen of Michigan. Plaintiff purchased Ranitidine-Containing Products in Michigan from approximately 1989 to December 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) prescription Zantac tablets and capsules, beginning in approximately 1989, manufactured by GSK; and (b) OTC Zantac tablets and capsules, from approximately 1995 until 2020, manufactured by GSK, Pfizer, BI, and Sanofi. For

the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

34. Plaintiff Lakisha Wilson (for the purpose of this paragraph, "Plaintiff") is a citizen of Michigan. Plaintiff purchased Ranitidine-Containing Products in Michigan from approximately 1997 to 2017. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC Zantac tablets and capsules, in or around 1997 and from approximately 2010 to 2011, manufactured by GSK, Pfizer, and BI. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Minnesota

35. Plaintiff Donald Northrup (for the purpose of this paragraph, "Plaintiff") is a citizen of Minnesota. Plaintiff purchased Ranitidine-Containing Products in Minnesota from approximately 2000 to 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included (a) OTC 75 mg Zantac tablets and capsules, from approximately 2000 to 2019, manufactured by Pfizer, BI, and Sanofi; and (b) prescription 150 mg Zantac tablets and capsules, beginning in approximatley 2000, manufactured by GSK. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions,

Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

36. Plaintiff John Scholl (for the purpose of this paragraph, "Plaintiff") is a citizen of Minnesota. Plaintiff purchased Ranitidine-Containing Products in North Dakota in approximately 2005, and in Minnesota from approximately 2005 to 2016. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) OTC 75 mg Zantac tablets and capsules, purchased in North Dakota in approximately 2005, manufactured by Pfizer; and (b) OTC 75 mg Zantac tablets and capsules, purchased in Minnesota from approximately 2005 to 2016, manufactured by Pfizer and BI. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in Minnesota, while a citizen of Minnesota, and Pfizer is the "Defendant" for the purposes of Plaintiffs' claims with respect to Plaintiff's purchases made in North Dakota, while a citizen of North Dakota. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Mississippi

37. Plaintiff Beverly Crosby (for the purpose of this paragraph, "Plaintiff") is a citizen of Mississippi. Plaintiff purchased Ranitidine-Containing Products in Mississippi from approximately 2000 to 2020. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC Zantac tablets and capsules, from approximately 2000 to 2014, manufactured by Pfizer and BI. Thus, Pfizer is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a result of Pfizer's breaches of

warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

38. Plaintiff John Rachal (for the purpose of this paragraph, "Plaintiff") is a citizen of Mississippi. Plaintiff purchased Ranitidine-Containing Products in Mississippi from approximately 2000 to October 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC 75 mg and 150 mg Zantac tablets and capsules, from approximately 2000 to 2019, manufactured by Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Nebraska

39. Plaintiff Gaylord Stauffer (for the purpose of this paragraph, "Plaintiff") is a citizen of Nebraska. Plaintiff purchased Ranitidine-Containing Products in Nebraska from 1997 to 2010 and from 2013 to 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC 75 mg and 150 mg Zantac tablets and capsules, from 1997 to 2010 and from 2013 to 2019, manufactured by GSK, Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and,

therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

New York

40. Plaintiff Benny Fazio (for the purpose of this paragraph, "Plaintiff") is a citizen of New York. Plaintiff purchased Ranitidine-Containing Products in New York from approximately 2000 to 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) prescription 150 mg Zantac tablets and capsules, from approximately 2000 to 2004, manufactured by GSK; and (b) OTC Zantac tablets and capsules, from approximately 2000 to 2019, manufactured by Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

41. Plaintiff Mary McCullen (for the purpose of this paragraph, "Plaintiff") is a citizen of New York. Plaintiff purchased Ranitidine-Containing Products in New York from approximately 1998 to February 2020. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included (a) OTC Zantac tablets and capsules, from approximately 1998 to 2019, manufactured by Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

North Carolina

42. Plaintiff Dennis Robbins (for the purpose of this paragraph, "Plaintiff") is a citizen of North Carolina. Plaintiff purchased Ranitidine-Containing Products in North Carolina from approximately 1985 to October 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included (a) prescription 150 mg Zantac tablets and capsules, from approximately 1985 to 1997, manufactured by GSK; and (b) OTC Zantac tablets and capsules, from approximately 1996 to 2019, manufactured by GSK, Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Ohio

43. Plaintiff Chris Troyan (for the purpose of this paragraph, "Plaintiff") is a citizen of Ohio. Plaintiff purchased Ranitidine-Containing Products in Ohio from approximately 2002 to 2020. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC Zantac tablets and capsules manufactured by Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

44. Plaintiff Michael Galloway (for the purpose of this paragraph, "Plaintiff") is a citizen of Ohio. Plaintiff purchased Ranitidine-Containing Products in Florida from approximately

1997 through 1999, and in Ohio from approximately 1999 through October 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) prescription 150 mg Zantac tablets and capsules, from approximately 1997 through 1999 in Florida, manufactured by GSK; (b) OTC Zantac tablets and capsules, from approximately 1997 through 1999 in Florida, manufactured by GSK and Pfizer; (c) prescription 150 mg Zantac tablets and capsules, beginning in approximately 1999 in Ohio, manufactured by GSK; and (d) OTC Zantac tablets and capsules, from approximately 1999 through October 2019 in Ohio, manufactured by Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in Florida while a citizen of Florida unless otherwise specified; and Pfizer is the "Defendant" with respect to Plaintiff's purchases made in Ohio while a citizen of Ohio. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Pennsylvania

45. Plaintiff Nicholas Hazlett (for the purpose of this paragraph, "Plaintiff") is a citizen of Pennsylvania. Plaintiff purchased Ranitidine-Containing Products in Maryland from approximately 2005 to 2007, and in Pennsylvania from approximately 2007 to 2020. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) prescription 15 mg/ml Zantac syrup, from approximately 2005 to 2007 in Maryland, manufactured by GSK; (b) prescription Zantac tablets and capsules, from approximately 2005 to 2007 in Maryland, manufactured by GSK; (c) OTC Zantac tablets and capsules, from approximately 2005 to 2007 in Maryland, manufactured by Pfizer and BI; (d)

prescription 15 mg/ml Zantac syrup, beginning in approximately 2007 in Pennsylvania, manufactured by GSK; (e) prescription Zantac tablets and capsules, beginning in approximately 2007 in Pennsylvania, manufactured by GSK; and (f) OTC Zantac tablets and capsules, from approximately 2007 to 2020 in Pennsylvania, manufactured by BI and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in Maryland while a citizen of Maryland. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Puerto Rico

46. Plaintiff Gloria Colon (for the purpose of this paragraph, "Plaintiff") is a citizen of Puerto Rico. Plaintiff purchased Ranitidine-Containing Products in Puerto Rico from approximately 1989 to 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) prescription Zantac tablets and capsules, beginning in approximately 1989, manufactured by GSK; and (b) OTC Zantac tablets and capsules, from approximately 1996 to 2019, manufactured by GSK, Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Tennessee

47. Plaintiff Dale Hunter (for the purpose of this paragraph, "Plaintiff") is a citizen of Tennessee. Plaintiff purchased Ranitidine-Containing Products in Tennessee from approximately 1995 to October 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) OTC 75 mg Zantac tablets and capsules, from approximately 2004 or 2005 to 2019, manufactured by Pfizer, BI, and Sanofi; and (b) prescription 150 mg Zantac tablets and capsules, beginning in approximately 1995, manufactured by GSK. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

48. Plaintiff Kenneth Hix (for the purpose of this paragraph, "Plaintiff") is a citizen of Tennessee. Plaintiff purchased Ranitidine-Containing Products in Tennessee from approximately 2015 to 2016, and in Michigan from approximately 2000 to 2015. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included the following: (a) OTC 75 mg Zantac tablets and capsules, from approximately 2000 to 2015 in Michigan, manufactured by Pfizer and BI; and (b) OTC 75 mg Zantac tablets and capsules, from approximately 2015 to 2016 in Tennessee, manufactured by BI. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in Michigan while a citizen of Michigan. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were

worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Texas

49. Plaintiff Sylvia Yoshida (for the purpose of this paragraph, "Plaintiff") is a citizen of Texas. Plaintiff purchased Ranitidine-Containing Products in Texas from approximately 2006 to 2017. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC Zantac tablets and capsules, from approximately 2006 to 2017, manufactured by Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

50. Plaintiff Ronda Lockett (for the purpose of this paragraph, "Plaintiff") is a citizen of Texas. Plaintiff purchased Ranitidine-Containing Products in Oklahoma from approximately 1983 to 1990 and 2001 to 2004; in Missouri from approximately 1990 to 2000; and in Texas from approximately 2001 to 2020. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) prescription Zantac tablets and capsules, from approximately 1983 to 1990 in Oklahoma, manufactured by GSK; (b) prescription Zantac tablets and capsules, from approximately 1990 to 1995 in Missouri, manufactured by GSK; (c) OTC Zantac tablets and capsules, from approximately 1996 to 2000 in Missouri, manufactured by GSK and Pfizer; and (d) OTC Zantac tablets and capsules, from approximately 2000 to 2020 in Texas, manufactured by Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in

Missouri while a citizen of Missouri, unless otherwise specified; and for the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in Texas while a citizen of Texas. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

51. Plaintiff Marianella Villanueva (for the purpose of this paragraph, "Plaintiff") is a citizen of Texas. Plaintiff purchased Ranitidine-Containing Products in Texas from approximately 2005 to 2020, and in South Carolina or about 2010. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) prescription Zantac tablets and capsules, beginning in approximately 2005 in Texas, manufactured by GSK; (b) OTC 75 mg and 150 mg Zantac tablets and capsules, from approximately 2005 to 2020 in Texas, manufactured by Pfizer, BI, and Sanofi; and (c) OTC 75 mg and 150 mg Zantac tablets and capsules, in or about 2010 in South Carolina, manufactured by BI. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in Texas while a citizen of Texas. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Virginia

52. Plaintiff Dan Zhovtis (for the purpose of this paragraph, "Plaintiff") is a citizen of Virginia. Plaintiff purchased Ranitidine-Containing Products in New York from approximately

2000 to 2016, and in Virginia from 2016 to September of 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) OTC Zantac tablets and capsules, from approximately 2000 to 2016 in New York, manufactured by Pfizer and BI; and (b) OTC 150 mg Zantac tablets and capsules, from approximately 2016 to September 2019 in Virginia, manufactured by BI and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in New York while a citizen of New York. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

Washington

53. Plaintiff Jonathan Ferguson (for the purpose of this paragraph, "Plaintiff") is a citizen of Washington. Plaintiff purchased Ranitidine-Containing Products in Oregon from approximately 1996 and 1999 to 2003; in Nevada from approximately 1996 to 1999; and in Washington from approximately 2003 to 2007 and 2012 to July 2018. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) OTC Zantac tablets and capsules, from approximately 1996 and 1999 to 2003 in Oregon, manufactured by GSK and Pfizer; (b) OTC Zantac tablets and capsules, from approximately 1996 to 1999 in Nevada, manufactured by GSK and Pfizer; and (c) OTC Zantac tablets and capsules, from approximately 2003 to 2007 and 2012 to July 2018 in Washington, manufactured by Pfizer, BI, and Sanofi. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims with respect to Plaintiff's purchases made in Oregon while a citizen of Oregon, unless otherwise specified; Pfizer is the "Defendant" with respect to Plaintiff's purchases made in

Nevada while a citizen of Nevada, unless otherwise specified; and Pfizer is the "Defendant" with respect to Plaintiff's purchases made in Washington while a citizen of Washington. As a result of Pfizer's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

54. Steve Fischer (for the purpose of this paragraph, "Plaintiff") is a citizen of Washington. Plaintiff purchased Ranitidine-Containing Products in Washington from approximately 2006 to 2019. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included OTC 150 mg Zantac tablets and capsules, in or around 2006, manufactured by Pfizer. Thus, Pfizer is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a result of Defendant's breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Defendant's wrongful conduct.

Wisconsin

55. Plaintiff Wendy Quezaire (for the purpose of this paragraph, "Plaintiff") is a citizen of Wisconsin. Plaintiff purchased Ranitidine-Containing Products in Wisconsin from approximately 2005 to 2020. The Ranitidine-Containing Products purchased by Plaintiff that are subject to the Complaint specifically included: (a) OTC Zantac tablets and capsules, from approximately 2005 to 2010, manufactured Pfizer and BI; and (b) prescription Zantac tablets and capsules, from approximately 2005 to 2010, manufactured by GSK. For the purposes of this Complaint, Pfizer is the "Defendant" for the purposes of Plaintiff's claims. As a result of Pfizer's

breaches of warranties, wrongful acts, and misrepresentations and omissions, Plaintiff purchased Ranitidine-Containing Products that were unsafe for human ingestion and, therefore, were worthless at the time of purchase. Thus, Plaintiff has suffered concrete injury in the form of economic damages as a result of Pfizer's wrongful conduct.

III. JURISDICTION & VENUE

56. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332, as amended by the Class Action Fairness Act of 2005 28 U.S.C. §1332(d)(2), because: (a) there are at least 100 class members; (b) the matter in controversy exceeds $5 million, exclusive of interests and costs; and (c) at least one Plaintiff is a citizen of a different state than at least one Defendant. In addition, this Court has supplemental jurisdiction over Plaintiffs' state law claims under 28 U.S.C. §1367.

57. This Court has personal jurisdiction over Pfizer because Pfizer has its principal place of business in New York, as well as under 18 U.S.C. §1965(b) and (d). This Court also has pendent personal jurisdiction over Defendant.

58. In addition and/or in the alternative, Pfizer and/or its agents or alter egos each have significant contacts with each of the states and territories of the United States because they designed, manufactured, tested, marketed, labeled, packaged, distributed, stored, and/or sold Ranitidine-Containing Products within each of the states and territories of the United States, and/or they derived revenue from the sale of their Ranitidine-Containing Products in each of the states and territories of the United States, through the purposeful direction of their activities to the states and territories of the United States and purposeful availment of the protections of the laws of the states and territories of the United States, such that personal jurisdiction would be proper in those states and territories under traditional notions of fair play and substantial justice.

59. Venue is proper in this District under 28 U.S.C. §1391(b) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District, and because Pfizer resides in this District, which has personal jurisdiction over Pfizer. Pfizer designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products, and otherwise conducted extensive business, within this District.

IV. BACKGROUND FACTS

A. The Science

1. The Creation of Ranitidine-Containing Products and Their Introduction to the Market

60. Pfizer designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine under the brand Zantac OTC.

a. GSK Develops Zantac Through a Flurry of Aggressive Marketing Maneuvers

61. Ranitidine belongs to a class of medications called histamine H_2-receptor antagonists (or H_2 blockers), which decrease the amount of acid produced by cells in the lining of the stomach. Other drugs within this class include cimetidine (branded Tagamet), famotidine (Pepcid), and nizatidine (Axid).

62. GSK-predecessor Smith, Kline & French discovered and developed Tagamet, the first H_2 blocker and the prototypical histamine H_2 receptor antagonist from which the later members of the class were developed.

63. GSK[7] developed Zantac specifically in response to the success of cimetidine. Recognizing the extraordinary potential of having its own H_2 blocker in the burgeoning anti-ulcer market, GSK was all too willing to ensure its drug succeeded at all costs.

[7] GSK, as it is known today, was created through a series of mergers and acquisitions: In 1989, Smith, Kline & French merged with the Beecham Group to form SmithKline Beecham plc. In

64. In 1976, scientist John Bradshaw, on behalf of GSK-predecessor Allen & Hanburys Ltd. synthesized and discovered ranitidine.

65. Allen & Hanburys Ltd., a then-subsidiary of Glaxo Laboratories Ltd., is credited with developing ranitidine and was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office in December 1978, which covered the ranitidine molecule.

66. In 1983, the FDA granted approval to Glaxo to sell Zantac, pursuant to the New Drug Application ("NDA") No. 18-703, and it quickly became GSK's most successful product – a "blockbuster." Indeed, Zantac became the first prescription drug in history to reach $1 billion in sales.

67. To accomplish this feat, GSK entered into a joint promotion agreement with Hoffmann-LaRoche, Inc., [redacted].[8] More salespersons drove more sales and blockbuster profits for GSK.

68. In June 1986, the FDA approved Zantac for maintenance therapy of duodenal ulcers and for treatment of patients with gastroesophageal reflux disease ("GERD").

69. [redacted].[9] In 1995, the FDA approved OTC Zantac 75 mg tablets through NDA 20-520. In 1998, the FDA approved OTC Zantac 75 mg effervescent tablets through NDA 20-745.

1995, Glaxo merged with the Wellcome Foundation to become Glaxo Wellcome plc. In 2000, Glaxo Wellcome plc merged with SmithKline Beecham plc to form GlaxoSmithKline plc and GlaxoSmithKline LLC.

[8] GSKZAN0000348881; GSKZAN0000348871.

[9] GSKZAN0000022775.

70. In 1998, GSK (Glaxo Wellcome plc) and Warner-Lambert Co. ended their partnership. As part of the separation, Warner-Lambert Co. retained control over the OTC NDA for Zantac and the Zantac trademark in the United States and Canada but was required to obtain approval from GSK prior to making any product or trademark improvements or changes. GSK retained rights to sell OTC Zantac outside of the United States and Canada,[10] and retained control over the Zantac trademark internationally.[11]

71. In 2000, Pfizer acquired Warner-Lambert Co. Pfizer controlled the Zantac OTC NDAs until December 2006.

72. In October 2000, GSK sold to Pfizer the full rights to OTC Zantac in the United States and Canada pursuant to a divestiture and transfer agreement. As part of that agreement, GSK divested all domestic Zantac OTC assets to Pfizer, including all trademark rights. The agreement removed the restrictions on Pfizer's ability to seek product line extensions or the approval for higher doses of OTC Zantac. GSK retained the right to exclusive use of the Zantac name for any prescription Ranitidine-Containing Product in the United States.

73. In October 2003, Pfizer submitted NDA 21-698 for approval to market OTC Zantac 150 mg. The FDA approved NDA 21-698 on August 31, 2004.

74. During the time that Pfizer owned the rights to OTC Zantac, GSK continued to manufacture the product.

75. [redacted]

[redacted]

[10] GSK also still held the right to sell prescription Zantac in the United States.

[11] PFI00245109.

[redacted].

76. [redacted]

77. GSK continued marketing prescription Zantac in the United States until 2017 and still holds the NDAs for several prescription formulations of Zantac. GSK continued to maintain manufacturing and supply agreements relating to various formulations of both prescription and OTC Zantac. According to its recent annual report, GSK claims to have "discontinued making and selling prescription Zantac tablets in 2017 . . . in the U.S."[13]

78. Boehringer Ingelheim owned and controlled the NDA for OTC Zantac between December 2006 and January 2017, and manufactured, marketed, and distributed the drug in the United States during that period.[14]

79. In 2017, Boehringer Ingelheim sold the rights of OTC Zantac to Sanofi pursuant to an asset swap agreement. As part of that deal, Sanofi obtained control and responsibility over Boehringer Ingelheim's entire consumer healthcare business, including the OTC Zantac NDAs. As part of this agreement, Boehringer Ingelheim and Sanofi entered into a manufacturing agreement wherein Boehringer continued to manufacture OTC Zantac for Sanofi.

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[12] PFI00191352.

[13] GlaxoSmithKline, plc, *Annual Report* 37 (2019), https://www.gsk.com/media/5894/annual-report.pdf.

[14] Boehringer Ingelheim also owned and controlled ANDA 074662.

80. Sanofi has controlled the OTC Zantac NDAs and marketed, sold, and distributed Zantac in the United States from January 2017 until 2019 when it issued a global recall and ceased marketing, selling, and distributing OTC Zantac. [redacted][15]

81. Throughout the time that Sanofi controlled the OTC Zantac NDAs, Boehringer Ingelheim Promeco, S.A. de C.V. and Patheon Manufacturing Services LLC manufactured the finished drug product.

82. Sanofi voluntarily recalled all brand OTC Zantac and ranitidine on October 18, 2019.

83. Pfizer and Boehringer Ingelheim have made demands for indemnification per the Stock and Asset Purchase Agreement against J&J for legal claims related to OTC Zantac products.

84. Sanofi has made a demand for indemnification against J&J pursuant to a 2016 Asset Purchase Agreement between J&J and Sanofi.

85. The times during which each Brand Manufacturer manufactured and sold branded Zantac are alleged below:

Manufacturer/ Repackager	**Product**	**Prescription or Over the Counter**	**Sale Start Date Year**	**Sale End Date Year**
GlaxoSmithKline	Pills, Syrup, and Injection	Prescription	1983	2019
GlaxoSmithKline/Warner Lambert	Pills	OTC	1995	1998
Pfizer	Pills	OTC	1995	2006
Boehringer Ingelheim	Pills	OTC	2007	2016
Sanofi	Pills	OTC	2017	2019

[15] SANOFI_ZAN_MDL_0000208478.

2. NDMA Is a Carcinogen Whose Dangerous Properties Are Well Established

86. According to the Environmental Protection Agency ("EPA"), "[N-Nitrosodimethylamine ("NDMA")] is a semivolatile organic chemical that forms in both industrial and natural processes."[16] It is one of the simplest members of a class of N-nitrosamines, a family of potent carcinogens. Scientists have long recognized the dangers that NDMA poses to human health. A 1979 news article noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[17] NDMA is no longer produced or commercially used in the United States except for research. Its only use today is to cause cancer in laboratory animals.

87. Both the EPA and the International Agency for Research on Cancer ("IARC") classify NDMA as a probable human carcinogen.[18]

88. The IARC classification is based upon data that demonstrates NDMA "is carcinogenic in all animal species tested: mice, rats, Syrian gold, Chinese and European hamsters, guinea-pigs, rabbits, ducks, mastomys, various fish, newts and frogs. It induces benign and malignant tumors following its administration by various routes, including ingestion and

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[16] U.S. Environmental Protection Agency, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[17] Jane Brody, *Bottoms Up: Alcohol in Moderation Can Extend Life*, The Globe & Mail (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger Grows as Officials Unable to Trace Poison in Reserve's Water*, The Globe & Mail (CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); Kyrtopoulos *et al*, *DNA Adducts in Humans After Exposure to Methylating Agents*, 405 Mut. Res. 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

[18] *See EPA Technical Fact Sheet*, *supra* n.16; Int'l Agency for Research on Cancer (IARC), *Summaries & Evaluations, N-NITROSODIMETHYLAMINE* (1978), http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html.

inhalation, in various organs in various species." Further, in 1978, IARC stated that NDMA "should be regarded for practical purposes as if it were carcinogenic to humans."[19]

89. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[20]

90. The Department of Health and Human Services ("DHHS") states that NDMA is reasonably anticipated to be a human carcinogen.[21] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[22]

91. The FDA considers NDMA a carcinogenic impurity[23] and chemical that "could cause cancer" in humans.[24] The FDA recognizes that NDMA is "known to be toxic."[25]

92. The World Health Organization states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."[26] NDMA

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[19] 17 Int'l Agency for Research on Cancer, *IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Some N-Nitroso Compounds* 151-52 (May 1978).

[20] *See EPA Technical Fact Sheet*, *supra* n.16.

[21] *Id.* at 3.

[22] *Id.*

[23] ApotexCorp_0000000786.

[24] FDA Statement, Janet Woodcock, Director – Ctr. for Drug Evaluation & Research, *Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine* (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.

[25] Amneal_prod 1 _ 0000002938.

[26] World Health Org., *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3d ed. 2008), https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf.

belongs to the so-called "cohort of concern" which is a group of highly potent mutagenic carcinogens that have been classified as probable human carcinogens.[27]

93. NDMA is among the chemicals known to the state of California to cause cancer (Title 27, California Code of Regulations, Section 27001), pursuant to California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

94. The European Medicines Agency ("EMA") has referred to NDMA as "highly carcinogenic." It recommended that "primary attention with respect to risk for patients should be on these highly carcinogenic N-nitrosamines" (including NDMA), and categorized NDMA as "of highest concern with respect to mutagenic and carcinogenic potential."[28]

95. In 1989, the Agency for Toxic Substances and Disease Registry (ATSDR) stated that it is "reasonable to expect that exposure to NDMA by eating, drinking or breathing could cause cancer in humans" and that the "carcinogenicity of orally-administered NDMA has been demonstrated unequivocally in acute, intermediate and chronic durations studies" in animals and "it is important to recognize that this evidence also indicates that oral exposures of acute and intermediate duration are sufficient to induce cancer." Moreover, "hepatoxicity has been demonstrated in all animal species that have been tested and has been observed in humans who were exposed to NDMA by ingestion or inhalation."[29]

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[27] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk, M7(R1), March 2017; https://database.ich.org/sites/default/files/M7_R1_Guideline.pdf.

[28] Nitrosamines EMEA-H-A5(3)-1490 - Assessment Report (europa.eu) (June 25, 2020), https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report_en.pdf.

[29] ATSDR Toxicological Profile For N-Nitrosodimethylamine (December 1989), http://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

96. The International Register of Potentially Toxic Chemicals (IRPTC 1988) lists regulations imposed by 13 countries for NDMA for occupational exposure, packing, storing and transport, disposal, and warns of its probable human carcinogenicity and its high level of toxicity by ingestion or inhalation.

97. The Occupational Safety and Health Administration classifies NDMA as "a carcinogen" that requires special and significant precautions along with specific hazard warnings.[30]

98. A review of the Brand Manufacturers' own internal documents reveals that there is simply no question of material fact that it has been widely known within the medical and scientific community for over 40 years that NDMA is toxic and a known carcinogen.

99. In September 2019, GSK [redacted]

100. [redacted]

[30] 29 C.F.R §1910.1003 (2012).

[31] GSKZAN0000236640.

[redacted][34]

101. [redacted]

[redacted]

32 GSKZAN0000369506.

33 GSKZAN0000257640.

34 *Id*.

35 GSKZAN0000163882.

36 *See* GSK Dear HCP Letter, (October 3, 2019), publicly available (for example, https://www.hpra.ie/docs/default-source/Safety-Notices/gsk-hcp-letter-03oct2019.pdf).

37 GSKZAN0000178581.

[redacted][38]

102. Likewise, Sanofi [redacted] *Id.*

103. Non-party Dr. Reddy's [redacted]

[38] GSKZAN0000172037.

[39] SANOFI_ZAN_MDL_0000169790.

[40] SANOFI_ZAN_MDL_0000206858.

[41] DRLMDL0000077291.

[42] DRLMDL0000070414.

[redacted][43]

104. [redacted]

105. Non-party Apotex [redacted][45]

106. Non-party Glenmark admitted in its recall notification letter that "a carcinogenic impurity, NDMA, has been found in ranitidine medications at levels exceeding the FDA allowable limit."[46]

107. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

108. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure – Valsartan, Losartan, and Irbesartan – because the medications contained nitrosamine impurities that do not meet the FDA's

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43 *Id.*

44 DRLMDL0000069991.

45 ApotexCorp_0000030734.

46 GiantEagle_MDL2924_00000303.

safety standards. Some of the manufacturers of those contaminated medications also are parties to this case. They include Sandoz and Teva.

109. This continued in 2020 when the FDA required recalls of numerous generic manufacturers' metformin, including metformin made by non-parties Apotex, Amneal, and Teva.[47]

110. NDMA is a genotoxin which interacts with DNA and may subsequently induce mutations. Genotoxins are not considered to have a safe threshold or dose due to their ability to alter DNA.

111. The FDA has set an acceptable daily intake ("ADI") level for NDMA at 96 ng. That means that consumption of 96 ng of NDMA a day would increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the level of NDMA exposure increases. However, any level above 96 ng is considered unacceptable.[48]

112. In studies examining carcinogenicity through oral administration, mice exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, cancers were observed in the liver, kidney, pancreas, and lung. In comparable hamster studies, cancers were observed in the liver, pancreas, and stomach. In comparable guinea-pig studies, cancers were observed in the liver and lung. In comparable rabbit studies, cancers were observed in the liver and lung.

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[47] U.S. Food & Drug Admin., FDA Updates and Press Announcements on NDMA in Metformin, https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin (current as of Jan. 06, 2021).

[48] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)* (Feb. 28, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

113. In other long-term animal studies in mice and rats utilizing different routes of exposures – inhalation, subcutaneous injection, and intraperitoneal (abdomen injection) – cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

114. Prior to the withdrawal of ranitidine, it was considered a category B drug for birth defects, meaning it was considered safe to take during pregnancy. Yet animals exposed to NDMA during pregnancy birthed offspring with elevated rates of cancer in the liver and kidneys.

115. NDMA is a very small molecule. That allows it to pass through the blood-brain and placental barrier. This is particularly concerning as ranitidine has been marketed for pregnant women and young children for years.

116. Exposure to high levels of NDMA has been linked to liver damage in humans.[49]

117. Numerous *in vitro* studies confirm that NDMA is a mutagen – causing genetic mutations in human and animal cells.

118. Overall, the animal data demonstrates that NDMA is carcinogenic in all animal species tested: mice; rats; Syrian golden, Chinese and European hamsters; guinea pigs; rabbits; ducks; mastomys; fish; newts; and frogs.

119. The EPA classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[50]

120. Pursuant to EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."[51]

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[49] *See EPA Technical Fact Sheet*, *supra* n.16.

[50] *Id.*

[51] *See* U.S. Envtl. Protection Agency, Risk Assessment Forum, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005), https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.

121. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. These studies consistently show increased risks of various cancers.

122. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 220 cases, researchers observed a statistically significant 700% increased risk of gastric cancer in persons exposed to more than 0.51 micrograms/day.[52]

123. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 micrograms/day.[53]

124. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at 0.179 micrograms/day.[54]

125. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that "*N*-nitroso compounds are potent carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.[55]

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[52] Pobel, *et al*., *Nitrosamine, Nitrate and Nitrite in Relation to Gastric Cancer: A Case-control Study in Marseille, France*, 11 Eur. J. Epidemiol. 67-73 (1995).

[53] La Vecchia, *et al*., *Nitrosamine Intake & Gastric Cancer Risk*, 4 Eur. J. Cancer Prev. 469-74 (1995).

[54] Rogers *et al*., *Consumption of Nitrate, Nitrite, and Nitrosodimethylamine and the Risk of Upper Aerodigestive Tract Cance*r, 5 Cancer Epidemiol. Biomarkers Prev. 29-36 (1995).

[55] Knekt, *et al*., *Risk of Colorectal and Other Gastro-Intestinal Cancers after Exposure to Nitrate, Nitrite and N-nitroso Compounds: A Follow-Up Study*, 80 Int. J. Cancer 852-56 (1999).

126. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, and pharynx cancer.[56]

127. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268 cases and a follow up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women" for all cancers, and that "NDMA was associated with increased risk of gastrointestinal cancers" including rectal cancers.[57]

128. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 1,760 cases, researchers found a statistically significant elevated association between NDMA exposure and rectal cancer.[58]

129. NDMA is also known to be genotoxic – meaning, it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both *in vivo* and *in vitro.* However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that "humans may be especially sensitive to the carcinogenicity of NDMA."[59]

130. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA: (a) can exacerbate existing but dormant (*i.e.* not malignant) tumor

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[56] Straif, *et al*., *Exposure to High Concentrations of Nitrosamines and Cancer Mortality Among a Cohort of Rubber Workers*, 57 Occup. Envtl. Med 180-87 (2000).

[57] Loh, *et al*., *N-nitroso Compounds and Cancer Incidence: The European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, 93 Am. J. Clinical Nutrition 1053-61 (2011).

[58] Zhu, *et al*., *Dietary N-nitroso Compounds and Risk of Colorectal Cancer: A Case-control Study in Newfoundland and Labrador and Ontario, Canada*, 111 Brit. J. Nutrition 6, 1109-17 (2014).

[59] World Health Org., *supra* n. 26.

cells; (b) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and (c) reduce the ability of the body to combat cancer as NDMA is immunosuppressive. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

3. NDMA Is Discovered In Ranitidine-Containing Products, Leading To Market Withdrawal

131. On September 9, 2019, pharmacy and testing laboratory Valisure LLC and ValisureRX LLC (collectively, "Valisure") filed a Citizen Petition calling for the recall of all Ranitidine-Containing Products due to detecting exceedingly high levels of NDMA when testing ranitidine pills using gas chromatography-mass spectrometry. FDA and European regulators started reviewing the safety of ranitidine with specific focus on the presence of NDMA.[60] This set off a cascade of recalls by Zantac manufacturers.

132. On September 13, 2019, the FDA's Director for Drug Evaluation and Research, Dr. Janet Woodcock, issued a statement warning that some ranitidine medicines may contain NDMA.[61]

133. On September 24, 2019, non-party Sandoz voluntarily recalled all of its Ranitidine-Containing Products due to concerns of a "nitrosamine impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled medicine."[62]

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[60] FDA Statement, Woodcock, *supra* n.24; Press Release, European Medicines Agency, *EMA to Review Ranitidine Medicines Following Detection of NDMA* (Sept. 13, 2019), https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma.

[61] FDA Statement, Woodcock, *supra* n.24.

[62] FDA News Release, U.S. Food & Drug Admin., *FDA Announces Voluntary Recall of Sandoz Ranitidine Capsules Following Detection of an Impurity* (Sept. 24, 2019), https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-sandoz-ranitidine-capsules-following-detection-impurity.

134. On September 26, 2019, non-partiesApotex, Walgreens, Walmart, and Rite Aid voluntarily recalled all ranitidine products and removed them from shelves.[63] Apotex issued a statement, noting that "Apotex has learned from the U.S. Food and Drug Administration and other Global regulators that some ranitidine medicines including brand and generic formulations of ranitidine regardless of the manufacturer, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA)."[64]

135. On September 28, 2019, non-party CVS stated that it would stop selling Zantac and its CVS Store-Brand ranitidine out of concern that it might contain a carcinogen.

136. On October 2, 2019, the FDA ordered manufacturers of ranitidine to test their products and recommended using a liquid chromatography with high resolution mass spectrometer ("LC-HRMS") testing protocol, which "does not use elevated temperatures."[65]

137. On October 8, 2019, GSK voluntarily recalled all Ranitidine-Containing Products internationally.[66] As part of the recall, GSK publicly acknowledged that unacceptable levels of

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[63] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Sept. 26, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[64] Company Announcement, U.S. Food & Drug Admin., *Apotex Corp. Issues Voluntary Nationwide Recall of Ranitidine Tablets 75mg and 150mg (All Pack Sizes and Formats) Due to the Potential for Detection of an Amount of Unexpected Impurity, N-nitrosodimethylamine (NDMA) Impurity in the Product* (Sept. 25, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-ranitidine-tablets-75mg-and-150mg-(all-pack-sizes-and-formats).

[65] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Oct. 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[66] Press Release, Gov. UK, *Zantac – MHRA Drug Alert Issued as GlaxoSmithKline Recalls All Unexpired Stock* (Oct. 8, 2019), https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock.

NDMA were discovered in Zantac and noted that "GSK is continuing with investigations into the potential source of the NDMA."[67]

138. On October 18 and 23, 2019, Sanofi and non-party Dr. Reddy's voluntarily recalled all of their Ranitidine-Containing Products.[68]

139. On October 28, 2019, non-party Perrigo voluntarily recalled all its Ranitidine-Containing Products .[69]

140. In its recall notice, Perrigo stated, "[a]fter regulatory bodies announced that ranitidine may potentially contain NDMA, Perrigo promptly began testing of its externally sourced ranitidine API (active pharmaceutical ingredient) and ranitidine-based products. On October 8, 2019, Perrigo halted shipments of the product based upon preliminary results. Based on the totality of data gathered to date, Perrigo has made the decision to conduct this voluntary recall."[70]

141. On November 1, 2019, the FDA announced the results of recent testing, finding unacceptable levels of NDMA in Ranitidine-Containing Products , and requested that drug makers

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[67] Justin George Varghese, *GSK Recalls Popular Heartburn Drug Zantac Globally After Cancer Scare*, Reuters (Oct. 8, 2019), https://www.reuters.com/article/us-gsk-heartburn-zantac/gsk-recalls-popular-heartburn-drug-zantac-globally-after-cancer-scare-idUSKBN1WN1SL.

[68] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Oct. 23, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[69] *Id.*

[70] Company Announcement, U.S. Food & Drug Admin., *Perrigo Company plc Issues Voluntary Worldwide Recall of Ranitidine Due to Possible Presence of Impurity, N-nitrosodimethylamine (NDMA) Impurity in the Product* (Oct. 23, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/perrigo-company-plc-issues-voluntary-worldwide-recall-ranitidine-due-possible-presence-impurity-n.

begin to voluntarily recall their Ranitidine-Containing Products if the FDA or manufacturers discovered NDMA levels above the acceptable limits.[71]

142. On December 4, 2019, the FDA issued a statement notifying consumers who wished to continue taking ranitidine to consider limiting their intake of nitrite-containing foods, *e.g.*, processed meats and preservatives like sodium nitrite.[72] This advice ***mirrored*** an admonition issued by Italian scientists in 1981 after finding that ranitidine reacted with nitrites *in vitro* to form toxic and mutagenic effects in bacteria. The prudent advice of Dr. de Flora published in October 1981 in *The Lancet* was to "avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals or by giving inhibitors of nitrosation such as ascorbic acid."[73]

143. If GSK had only heeded Dr. de Flora's advice in 1981, millions of people might have avoided exposure to NDMA formed as a result of ranitidine's interaction with the human digestive system.

144. Between November 1, 2019 and February 27, 2020, non-parties Amneal, Glenmark recalled their products from the market, citing NDMA concerns.[74]

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[71] U.S. Food & Drug Admin., Laboratory Tests | Ranitidine, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine (current as of Nov. 1, 2019).

[72] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Dec. 4, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[73] Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, The Lancet, Oct. 31, 1981, at 993-94.

[74] *See generally* U.S. Food & Drug Admin., FDA Updates and Press Announcements on NDMA in Zantac (ranitidine), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine (current as of Apr. 16, 2020).

145. On January 2, 2020, research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that the ranitidine molecule is heat-liable and under certain temperatures progressively accumulates NDMA.

146. Emery's Citizen Petition outlined its substantial concern that ranitidine is a time- and temperature-sensitive pharmaceutical product that develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage. Emery requested that the FDA issue a directive to manufacturers to clearly label ranitidine with a warning that "by-products that are probable carcinogens can be generated if exposed to heat." In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine products in temperature-controlled vehicles.[75]

147. In response,[76] on April 1, 2020, the FDA recounted that a recall is an "effective methods[sic] of removing or correcting defective FDA-regulated products . . . particularly when those products present a danger to health."[77] The FDA sought the voluntary consent of manufacturers to accept the recall "to protect the public health from products that present a risk of injury."[78] The FDA found that the recall of all Ranitidine-Containing Products and a public warning of the recall was necessary because the "product being recalled presents a serious health

[75] Emery Pharma FDA Citizen Petition (Jan. 2, 2020) https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/.

[76] Letter of Janet Woodcock, U.S. Food & Drug Admin., Docket No. FDA-2020-P-0042 (Apr. 1, 2020), https://emerypharma.com/wp-content/uploads/2020/04/FDA-2020-P-0042-CP-Response-4-1-2020.pdf.

[77] *Id.* at 5 (citing 21 CFR 7.40(a)).

[78] *Id.*

risk."[79] The FDA therefore sent Information Requests to all applicants and pending applicants of Ranitidine-Containing Products "requesting a market withdrawal."[80]

148. The FDA found its stability testing raised concerns that NDMA levels in some Ranitidine-Containing Products stored at room temperature can increase with time to unacceptable levels. In the same vein, FDA testing revealed that higher NDMA levels were found as the products approached their expiration dates. The FDA's testing eroded the agency's confidence that any Ranitidine-Containing Product would remain stable through its labeled expiration date. Consequently, the FDA requested a market withdrawal of all ranitidine products. The FDA also announced to the public that the Agency's laboratory tests indicate that temperature and time contribute to an increase in NDMA levels in some ranitidine products. The FDA's decision to withdraw the drug rendered moot Emery's request for temperature-controlled shipping conditions.

149. The FDA's reaction was consistent with comparable regulatory action throughout the world. Before the FDA acted, over 43 different countries and jurisdictions restricted or banned Ranitidine-Containing Products.[81]

150. The European Medicines Agency ("EMA"), the European Union's equivalent to the FDA, through an Article 31 Referral, determined the sale of all Ranitidine-Containing Products should be suspended on September 19, 2019. On April 30, 2020, the Human Medicines Committee of the EMA "has recommended the suspension of all ranitidine medicines in the EU due to the presence of low levels of an impurity called N-nitrosodimethylamine (NDMA)." The EMA

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[79] *Id.* at 7.

[80] *Id.* at 10 n.43.

[81] Margaret Newkirk & Susan Berfield, *FDA Recalls Are Always Voluntary and Sometimes Haphazard-and The Agency Doesn't Want More Authority to Protect Consumers*, Bloomberg Businessweek (Dec. 3, 2019), https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/.

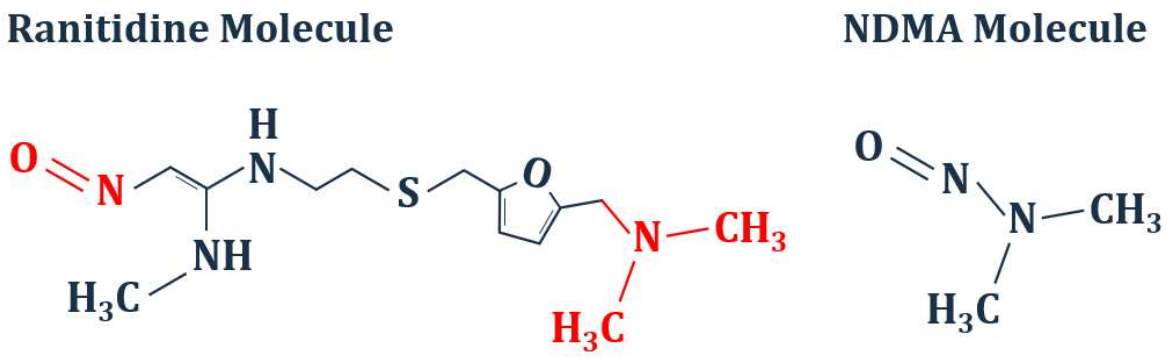
recognizes NDMA as a probable human carcinogen and issued a "precautionary suspension of these medicines in the EU" because "NDMA has been found in several ranitidine medicines above levels considered acceptable, and there are unresolved questions about the source of the impurities."[82]

151. On September 17, 2020, after a ranitidine manufacturer requested that the EMA re-examine its decision and permit ranitidine to be marketed again in the EU, the EMA confirmed its prior recommendation to suspend all ranitidine medicines in the EU due to the presence of NDMA, noting that it is a probable human carcinogen and that there is evidence that NDMA forms from the degradation of ranitidine itself with increasing levels seen over shelf life.[83]

4. How Ranitidine Transforms Into NDMA

152. The ranitidine molecule itself contains the constituent molecules to form NDMA. *See* Figure 1.

Figure 1 – Diagram of Ranitidine & NDMA Molecules



[82] Eur. Med. Agency, *Suspension of Ranitidine Medicines in the EU* (Apr. 30, 2020), https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-suspension-ranitidine-medicines-eu_en.pdf.

[83] Eur. Med. Agency, *EMA Confirms Recommendation to Suspend All Ranitidine Medicines in the EU* (Nov. 24, 2020), https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-ema-confirms-recommendation-suspend-all-ranitidine-medicines-eu_en.pdf.

153. The degradation occurs independently in two parts of the ranitidine molecule, with the products of the degradation combining to produce NDMA.

154. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the U.S. water supply.[84] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater-treatment plants were specifically linked to the presence of ranitidine.[85]

155. The high levels of NDMA observed in Ranitidine-Containing Products are a function of various factors. The ranitidine molecule internally degrades to form NDMA. The degradation of ranitidine can increase over time under normal storage conditions, but more so with exposure to heat and/or humidity. Once in the body, ranitidine continues to degrade and can yield increasing levels of NDMA in the human digestive system, and when it interacts with nitrogenous products.

a. Early Understandings as to Formation of NDMA in the Environment of the Human Stomach

156. When the ranitidine molecule is exposed to the acidic environment of the stomach, particularly when accompanied by nitrites (a chemical commonly found in heartburn-inducing foods), the Nitroso molecule (0=N) and the DMA molecule (H_3C-N-CH_3) break off and reform as NDMA.

157. In 1981, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, published the results of experiments he conducted on ranitidine in the well-known journal, *The*

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[84] Ogawa *et al.*, *Purification and Properties of a New Enzyme, NG, NG-dimethylarginine Dimethylaminohydrolase, from Rat Kidney*, 264 J. Bio. Chem. 17, 10205-209 (1989).

[85] Mitch *et al.*, *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 Env. Eng. Sci. 5, 389-404 (2003).

Lancet. When ranitidine was exposed to human gastric fluid in combination with nitrites, his experiment showed "toxic and mutagenic effects."[86] Dr. de Flora hypothesized that these mutagenic effects could have been caused by the "formation of more than one nitroso derivative [which includes NDMA] under our experimental conditions." *Id.* Dr. de Flora cautioned that, in the context of ranitidine ingestion, "it would seem prudent to … suggest[] a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals."[87] *Id.*

158. GSK knew of Dr. de Flora's publication because, two weeks later, GSK responded in *The Lancet*,[88] claiming that the levels of nitrite needed to induce the production of nitroso derivatives (*i.e.*, NDMA) were not likely to be experienced by people in the real world.[89]

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[86] De Flora, *supra* n.73.

[87] This admonition came two years before the FDA approved Zantac in 1983. Notwithstanding, in 1998 GSK applied for and obtained an indication for OTC Zantac "[f]or the prevention of meal-induced heartburn at a dose of 75 mg taken 30 to 60 minutes prior to a meal." *See* Ctr. for Drug Eval. & Research, *Approval Package* (June 8, 1998), https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20520s1_Zantac.pdf. So GSK specifically invited patients to take Zantac shortly before eating heartburn-inducing food.

[88] R. T., Brittain *et al*., *Safety of Ranitidine*, *The Lancet* 1119 (Nov. 14, 1981).

[89] This response reflects GSK's reputation for "adopting the most combative, scorched-earth positions in defense of its brands." Jim Edwards, *GSK's Alleged Coverup of Bad Avandia Data: A Snapshot of Its Poisonous Corporate Culture*, Moneywatch (July 13, 2010) https://www.cbsnews.com/news/gsks-alleged-coverup-of-bad-avandia-data-a-snapshot-of-its-poisonous-corporate-culture/. GSK has no compunction against distorting objective science to maintain lucrative monopoly franchises. Its egregious conduct surrounding Zantac is no isolated incident. GSK endangered patient health while reaping billions of dollars in profits from Paxil, Wellbutrin, and Avandia. It was involved in covering up scientific data, offering illegal kickbacks to prescribing physicians, intimidating witnesses, and defrauding Medicare to profit from these medicines. After Congressional hearings into this outrageous misbehavior, GSK's actions resulted in a criminal investigation and the then-largest guilty plea by a pharmaceutical company for fraud and failure to report safety data in the country's history. *Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia*, Senate Comm. on Finance, 111th Cong.2d Sess. 1 (Comm. Print Jan. 2010); U.S. Dep't of Justice, *GlaxoSmithKline to Please Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report. There is currently an open investigation of GSK and Sanofi being conducted by the Department of Justice relating to the failure to disclose to the federal government

159. GSK attended an FDA Advisory Committee in May 1982 where its representative testified and presented evidence relating to the safety of Zantac, including the potential for ranitidine to form nitrosamines. However, GSK failed to disclose its new evidence relating to ranitidine and the formation of a nitrosamine, specifically the formation of NDMA.[90]

160. One month later, in June 1982, GSK submitted its draft Summary Basis of Approval and labeling for Zantac. Again, GSK failed to submit or otherwise disclose its new evidence relating to ranitidine and the formation of NDMA.[91]

161. In its submission to the FDA, GSK discussed its findings from internal studies performed in 1980 that ranitidine formed a different nitrosamine, n-nitroso-nitrolic acid, a potent mutagen, but explained that these results had no "practical clinical significance"[92]:

> Although N-nitroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine, as an unrealistically large amount of nitrite needs to be present to form and maintain the nitrosamine. For this reason, and also because ranitidine was not carcinogenic in life-span studies in rodents, the in vitro nitrosation of ranitidine to a mutagenic nitrosamine does not seem to have practical clinical significance.

162. In 1980 – before Zantac was approved by the FDA – GSK conducted another study to examine, among other things, how long-term use of ranitidine could affect the levels of nitrite

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information about the potential presence of NDMA in Zantac. https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2020_07_29_HY_financial_report_EN.pdf.

[90] GSKZAN0000050413.

[91] GSKZNDAA0000071900.

[92] Excerpted from the Summary Basis of Approval submitted to the FDA to obtain approval of Zantac in the early 1980s. This document was obtained through a Freedom of Information Act request to the FDA.

in the human stomach.[93] Remarkably, GSK admitted that ranitidine use caused the proliferation of bacteria in the human stomach that are known to convert nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GSK acknowledged this could increase the risk of forming nitrosamines and, in turn, cancer, but then dismissed this risk because people were allegedly only expected to use Ranitidine-Containing Products for a short-term period:

> The importance of this finding is not clear. High levels of nitrite could react with certain organic compounds to form nitrosamines, which are known carcinogens. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies. Ranitidine is recommended only for short-term use and carcinogenic risk, if any, should thus be minimized.

163. GSK knew – and indeed specifically admitted – that ranitidine could react with nitrite in the human stomach to form nitrosamines and, at the same time, that long-term use of ranitidine could lead to elevated levels of nitrite in the human stomach. GSK also knew but did not disclose that it had new evidence showing that NDMA was generated by ranitidine under certain conditions.

164. In response to Dr. de Flora's findings, in 1982, GSK conducted a clinical study specifically investigating gastric contents in human patients.[94] The study, in part, specifically measured the levels of N-Nitroso compounds in human gastric fluid. GSK indicated that there were no elevated levels, and even published the results of this study five years later, in 1987. The study, however, was flawed. It did not use gold-standard mass spectrometry to test for NDMA, but instead, used a process that could not measure N-nitrosamines efficiently. And worse, in the

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[93] The results of this study are discussed in the Summary Basis of Approval, obtained from the FDA.

[94] Thomas *et al.*, *Effects of One Year's Treatment with Ranitidine and of Truncal Vagotomy on Gastric Contents*, 6 Gut. Vol. 28, 726-38 (1987).

testing it did do, GSK refused to test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded."[95] In other words, GSK intentionally engineered the study to exclude the very samples most likely to contain a dangerous carcinogen.

165. Given the above information that was disclosed relating to the nitrosation potential and formation of nitrosamines, it is shocking that GSK conducted an internal study to assess the formation of NDMA and found that ranitidine, when exposed to sodium nitrite, formed hundreds of thousands of nanograms of NDMA. The GSK study was never published or disclosed to the public.

166. In 1983, the same year GSK started marketing Zantac in the United States, seven researchers from the University of Genoa published a study discussing ranitidine and its genotoxic effects (ability to harm DNA).[96] The researchers concluded "it appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing DNA damage in mammalian cells." *Id.*

167. Then, again in 1983, Dr. de Flora, along with four other researchers, published their complete findings.[97] The results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine." Again, the authors noted that, "the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals." This admonition carries weight considering GSK's

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95 *Id.* at 730.

96 Maura *et al*., *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 Tox. Lttrs. 97-102 (1983).

97 De Flora *et al*., *Genotoxicity of Nitrosated Ranitidine*, 4 Carcinogenesis 3, 255-60 (1983).

studies indicate that long-term ranitidine consumption, itself, leads to elevated levels of nitrites in the human gut.

168. In addition, as multiple [redacted].

169. [redacted][99]

170. However, in 1985, [redacted]

[98] SANOFI_ZAN_MDL-0000033849-SANOFI_ZAN_MDL_0000033891, at SANOFI_ZAN_MDL_0000033873.

[99] GSKZNDAA0000072103-GSKZNDAA0000072128.

[100] GSKZAN0000369313, [redacted]

[redacted][101]

[redacted]

171. The high instability of the ranitidine molecule was elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed.[102] These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in the environment of water-treatment plants that supply many U.S. cities with water.

172. In 2002, researchers conducted a controlled study to evaluate the concentration of nitrosamines, including NDMA, in the gastric fluid and urine in children with gastritis before and after four to six weeks of treatment with ranitidine.[103] The study reported statistically significant increases in the nitrosamine concentration, including NDMA, in the gastric juice and urine in 93.3% of children after taking ranitidine for only four weeks. The researchers noted that

[101] GSKZNDAA0000636549.

[102] Le Roux *et al*., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 Envtl. Sci. Tech. 20, 11095-103 (2012).

[103] [redacted]

nitrosamines belong to the most potent known carcinogens and no organisms have been found that would be resistant to the harmful effects, that neoplastic lesions induced by nitroso compounds may develop in any organ, and that nitrosamines induced a wide spectrum of tumors in studies using animal models.[104] In addition, the authors noted specifically that NDMA induced similar symptoms of acute poisoning in humans and animals. They advised that prophylactic measures to avoid nitrosamine formation include a diet high in fruits and inclusion of ascorbic acid as well as limiting intake of processed meat. The conclusion was that ranitidine should only be recommended in children after careful consideration.[105]

173. Despite the direct evidence that children taking ranitidine were being exposed to dangerously high levels of carcinogenic nitrosamines including NDMA, which each Brand Manufacturer knew or should have known, Pfizer recklessly continued to market and promote Zantac and/or ranitidine as safe and effective for children.

174. Similarly, in 2016, researchers at Stanford University conducted an experiment on healthy adult volunteers.[106] They measured the NDMA in urine of healthy individuals over the course of 24 hours, administered one dose of ranitidine, and then measured the NDMA in the urine of the same individuals for another 24 hours. The study reported that on average, the level of NDMA increased by 400 times, to approximately 47,000 ng. The only change during that 24-hour period was the consumption of ranitidine. In the study, the scientists further explained that

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[104] *Id*.

[105] *Id*.

[106] Zeng *et al*., *Oral intake of Ranitidine Increases Urinary Excretion of N-nitrosodimethylamine*, 37 Carcinogenesis 625-34 (2016). While this study was recently retracted due to errors in its testing method, its publication put the Brand Manfuacturers on notice that ranitidine forms NDMA, particularly when subjected to heat, posing a risk of harm to those who consume it, and thus should have prompted the Brand Manufacturers to conduct thorough research and analysis on that issue (including testing their pills using gas chromatography-mass spectrometry).

previous studies have indicated a high metabolic conversion rate of NDMA, meaning it will be processed by the human body. This study showed that ranitidine generates NDMA in the human body.

175. Valisure is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO") – an accreditation recognizing the laboratories technical competence for regulatory purposes. Valisure's mission is to help ensure the safety, quality, and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses. Valisure tested ranitidine first by subjecting it to higher temperature and also tested it in conditions simulating the stomach.

176. In its September 9, 2019 Citizen's Petition to the FDA,[107] Valisure disclosed as part of its testing of Ranitidine-Containing Products that in every lot tested there were exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng.[108] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below:

Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol		
150 mg Tablets or equivalent	**Lot #**	**NDMA per tablet (ng)**

[107] Valisure, *Citizen Petition on Ranitidine* (Sept. 9, 2019), https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf.

[108] U.S. Food & Drug Admin., *Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, FY19-005-DPA-S* (Jan. 28, 2019).

Reference Powder	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311
Zantac (mint), CVS	9AE2864	3,267,968
Ranitidine, Equate	9BE2772	2,479,872
Ranitidine (mint), Equate	8ME2642	2,805,259
Ranitidine, Strides	77024060A	2,951,649

177. This testing by GC-MS demonstrates the instability of the ranitidine molecule and its propensity to break down under higher temperatures.

178. Valisure was concerned that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameter of 130 °C in the FDA recommended GC/MS protocol. So Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37 °C, the average temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

179. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF": 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF": 50 mM potassium chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) were used alone and in combination with various concentrations of nitrite, which is commonly ingested in foods like processed meats and is elevated in the stomach by antacid drugs. The inclusion of nitrite in gastric fluid testing is commonplace and helps simulate the environment of a human stomach.

180. Indeed, Ranitidine-Containing Products were specifically advertised to be used when consuming foods containing high levels of nitrates, such as tacos or pizza.[109]

181. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present, demonstrating proof of concept and as shown below:

Table 2 – Valisure Biologically Relevant Tests for NDMA Formation

Ranitidine Tablet Studies	**NDMA (ng/mL)**	**NDMA per tablet (ng)**
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid	Not Detected	Not Detected
Simulated Intestinal Fluid	Not Detected	Not Detected
SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected
SGF with 25 mM Sodium Nitrite	236	23,600
SGF with 50 mM Sodium Nitrite	3,045	304,500

182. Following the release of Valisure Citizen's Petition, the FDA conducted additional laboratory tests, which showed NDMA levels in all ranitidine samples it tested, including API and the finished drug, both tablets and syrup. The FDA developed SGF and SIF models to use with the LC-MS testing method to estimate the biological significance of *in vitro* findings. These models are intended to detect the formation of NDMA in systems that approximate the stomach and intestine.

183. When the scientific data is assessed overall, the literature demonstrates that the ingestion of ranitidine already containing NDMA combined with the presence of human-relevant

[109] *See, e.g.*, Zantac television commercial, *Family Taco Night*, https://www.ispot.tv/ad/dY7n/zantac-family-taco-night; Zantac television commercial, *Spicy*, https://youtu.be/jzS2kuB5_wg; Zantac television commercial, *Heartburn,* https://youtu.be/Z3QMwkSUlEg; Zantac television commercial, *Zantac Heartburn Challenge*, https://youtu.be/qvh9gyWqQns.

levels of nitrite in the stomach – a substance that is commonly found in foods that induce heartburn and that is known to be elevated in people taking ranitidine for longer than a month – the ranitidine molecule transforms into more NDMA which would dramatically increase a person's risk of developing cancer.

b. Formation of NDMA in Other Organs of the Human Body

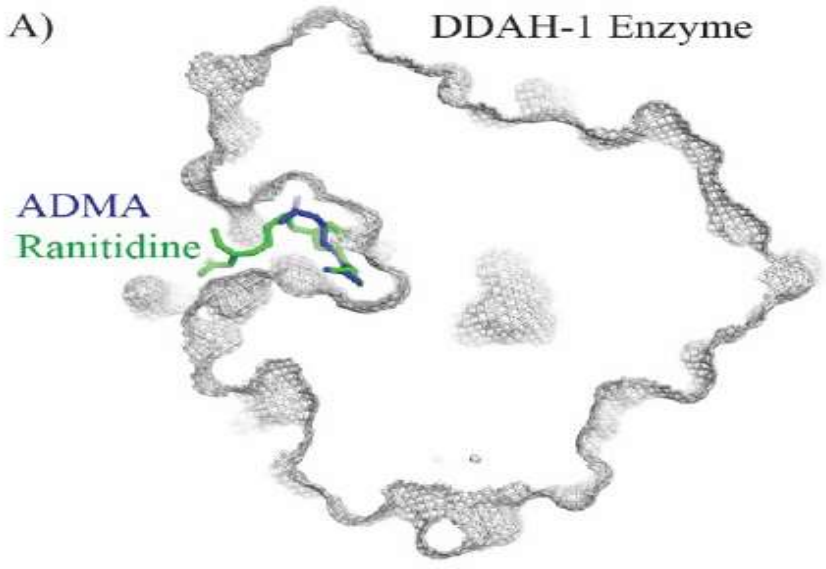
184. In addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH"), which can occur in other tissues and organs separate from the stomach.

185. Valisure explained that liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential pathways, particularly in weak acidic conditions such as that in the kidney or bladder. The original scientific paper detailing the discovery of the DDAH enzyme in 1989 specifically comments on the propensity of DMA to form NDMA: "This report also provides a useful knowledge for an understanding of the endogenous source of dimethylamine as a precursor of a potent carcinogen, dimethylnitrosamine [NDMA]."[110]

186. Valisure reported as illustrated in Figure 2, below, computational modelling demonstrates that ranitidine (shown in green) can readily bind to the DDAH-1 enzyme (shown as a cross-section in grey) in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine ("ADMA," shown in blue).

[110] Ogawa, *et al*., *supra* n.84.

Figure 2 – Computational Modelling of Ranitidine Binding to DDAH-1 Enzyme



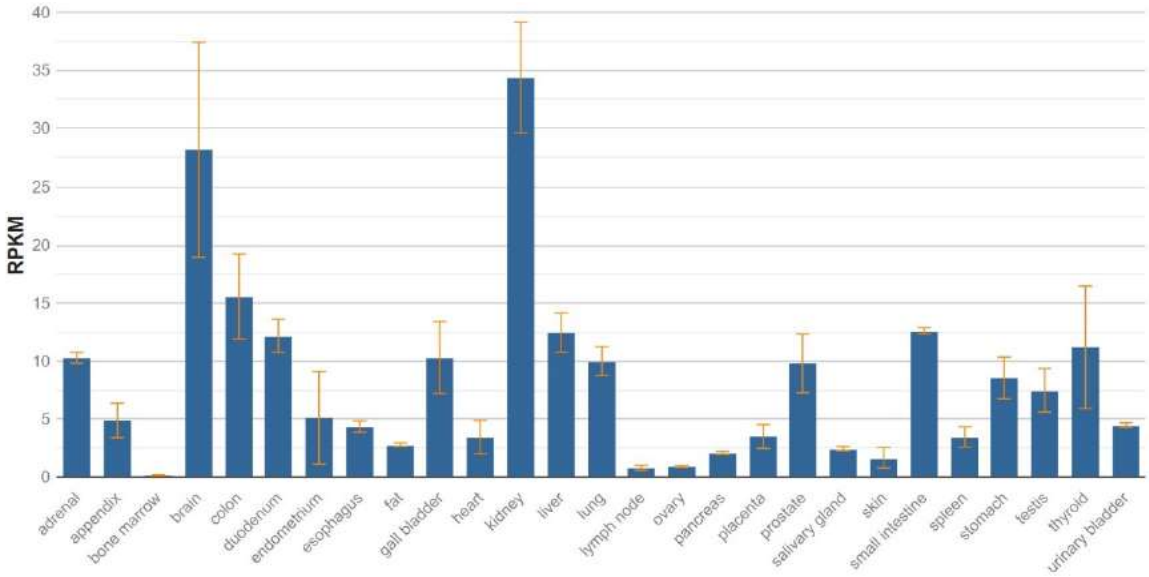
B)

	Predicted Affinity (kcal/mol)
ADMA	-5.9 ± 0.2
Ranitidine	-6.1 ± 0.1

187. Valisure reported that these results suggest that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of the DDAH-1 gene is useful for identifying organs most susceptible to this action.

188. Figure 3 below, derived from the National Center for Biotechnology Information, illustrates the expression of the DDAH-1 gene in various tissues in the human body.

Figure 3 – Expression levels of DDAH-1 enzyme by Organ



189. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the brain, colon, liver, small intestine, stomach, bladder, and prostate. Valisure noted that this offers both a general mechanism for NDMA formation in the human body from ranitidine and specifically raises concern for the effects of NDMA on numerous organs.

190. The possible enzymatic reaction of ranitidine to DDAH-1, or other enzymes, suggests that high levels of NDMA can form throughout the human body. Indeed, ranitidine metabolizes and circulates throughout the human body, crossing the placental and blood-brain barrier, within 1-2 hours. When ranitidine interacts with the DDAH-1 enzyme in various organs throughout the body, it breaks down into NDMA. This observation is validated by the Stanford study, discussed above.

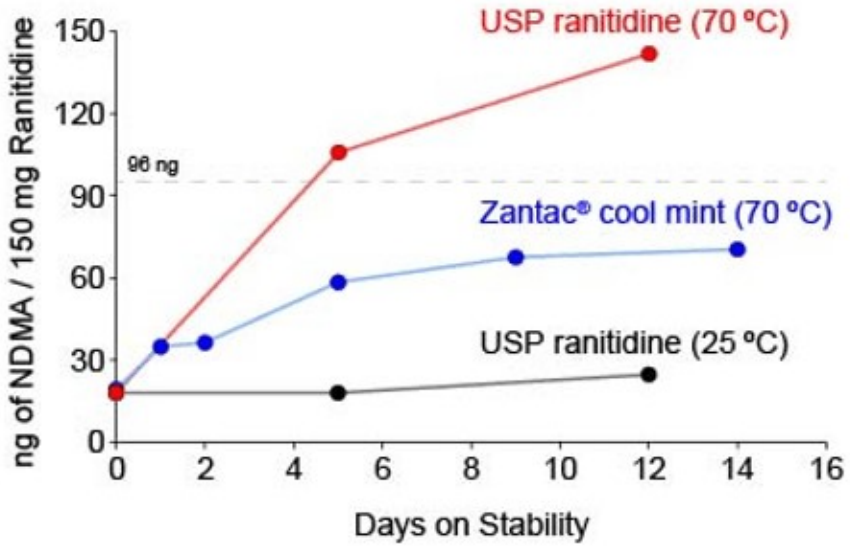
c. Formation of NDMA by Exposure to Heat, Moisture, and/or Time

191. The risk of creating NDMA by exposing ranitidine to heat has been well-known and documented. Early studies, including the one conducted by GSK in the early 1980s, demonstrated that nitrosamines were formed when ranitidine was exposed to heat. This point was underscored in the Valisure petition, which initially used a high-heat testing method.

192. In response to Valisure, on October 2, 2019, the FDA recommended that researchers use the LC-HRMS protocol for detecting NDMA in ranitidine because the "testing method does not use elevated temperatures" and has been proven capable of detecting NDMA.

193. On January 2, 2020, Emery, an FDA-certified pharmaceutical testing laboratory, conducted a series of tests on ranitidine. The researchers exposed ranitidine to 70 ˚C for varying periods of time. The results showed that increasing levels of NDMA formed based on exposure to heat. As reported by Emery, the following diagram reveals how NDMA accumulates over time when exposed to 70 ˚C:

Figure 4 – Rate of Development of NDMA when Exposed to Heat



194. The researchers cautioned:

> NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures, which would be routinely reached during shipment and during storage. More importantly, these conditions occur post-lot release by the manufacturer. Hence, while NDMA levels in ranitidine may be acceptable at the source, they may not be so when the drug is purchased and subsequently at the time of consumption by the consumer.[111]

195. The results of this data demonstrate that in normal transport and storage, and especially when exposed to heat or humidity, the ranitidine molecule systematically breaks down into NDMA, accumulating over time in the finished product. Considering Ranitidine-Containing Products have an approved shelf life of 36 months, the possibility of the drug accumulating dangerously high levels of NDMA prior to consumption is very real – a point underscored by the FDA's swift removal of the product from the market.

196. In fact, the FDA acknowledged that testing revealed that NDMA levels in ranitidine products stored at room temperature can increase with time to unacceptable levels.[112]

197. In 2019, the findings by Valisure unleashed an avalanche of regulatory authorities throughout the world demanding that the manufacturers of Zantac and/or ranitidine conduct testing of their products for the presence of NDMA as well as investigate the root cause as to how NDMA was being generated. In April 2020, the FDA requested that manufacturers immediately remove all Ranitidine-Containing Products from the market.

198. In the interim between the Valisure findings being released to the public and the FDA announcement requesting recall of all ranitidine products in April 2020, the manufacturers were investigating the root cause of NDMA in their products.

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[111] Emery Pharma, *Emery Pharma Ranitidine: FDA Citizen Petition* (Jan. 2, 2020), https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/.

[112] Woodcock Letter, *supra* n.76.

199. After undertaking an investigation, GSK concluded that "the presence of NDMA in ranitidine drug substance is due to a slow degradation reaction occurring primarily in the solid state. The two constituent parts of NDMA, the nitroso group and the dimethylamino group, are both derived from internal degradation reactions which occur at slow rates with the ranitidine molecule."[113] Unsurprisingly, GSK [redacted][114] In addition, GSK's testing revealed [redacted][115]

200. Similarly, Sanofi [redacted][116]

201. [redacted][117]

[113] GSKZAN0000052019-GSKZAN0000052127.

[114] *Id*. at 2.

[115] *Id*. at 12.

[116] SANOFI_ZAN_MDL_0000151458.

[117] SANOFI_ZAN_MDL_0000166517-527, at 11.

202. Brand Manufacturers could independently dictate the conditions under which API was transported to them. The labeling requirements do not apply to transporting API, in part because the finished product and API are packaged differently and may degrade under different conditions.

203. Based upon the documents produced by Brand Manufacturers and based upon further information and belief, Brand Manufacturers failed to ensure that their Ranitidine-Containing Products (in both API and finished dose form) were kept safely from excessive heat and humidity.[118]

5. Evidence Directly Links Ranitidine Exposure to Cancer

204. In addition to numerous epidemiology studies examining how NDMA causes cancer in humans, researchers have also specifically looked at ranitidine and found an association with cancer.

205. One epidemiology study, published in 2004, showed that men taking either ranitidine or cimetidine (Tagamet) had increased risks of bladder cancer.[119]

[118] *See, e.g.*, BOE_ZAN_MDL_0000203482 [redacted] DRLMDL0000087754 [redacted] DRLMDL0000077957 [redacted]

[119] D. Michaud *et al.*, *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 Cancer Epi. Biomarkers & Prevention 250-54 (Feb. 2004).

206. In another epidemiology study, published in 2008, specifically designed to look at breast cancer, ranitidine was shown to more than double the risk, an effect that was even more pronounced in those with specific gene mutations.[120]

207. Another epidemiological study, published in 2000, looking at various cancer risks and histamine H_2-receptor antagonists (or H_2 blockers), including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer.[121] Of particular note, the study indicated that people under the age of 60 who took ranitidine were five times more likely to develop prostate cancer. In addition, there was more than a doubling of the risk of pancreatic cancer with ranitidine use.

208. A study published in 2018, demonstrated an increased risk of liver cancer associated with use of ranitidine in comparison with other H_2 blockers in the class. The purpose of the study was to determine whether there was an increased risk of liver cancer associated with proton pump inhibitors, a different class of medications indicated for the treatment of GERD. This finding is particularly notable as the authors adjusted for variables.[122]

209. In 2018, a study found an increased risk in hepatocellular carcinoma associated with use of H_2 blockers.[123] The authors were evaluating the risk of cancer in association with proton pump inhibitors and looked at H_2 blockers as a confounder. The study only considered use

[120] Robert W. Mathes *et al*., *Relationship Between Histamine2-receptor Antagonist Medications and Risk of Invasive Breast Cancer*, 17 Cancer Epi. Biomarkers & Prevention 1, 67-72 (2008).

[121] Laurel A Habel *et al*., *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 9 Pharmacoepidemiology & Drug Safety 149-55 (2000).

[122] Kim Tu Tran *et al*., *Proton Pump Inhibitor and Histamine-2 receptor Antagonist Use and Risk of Liver Cancer in Two Population-based Studies*, 48 Alimentary Pharmacology & Therapeutics 1, 55-64 (2018).

[123] Y-H J Shao *et al*., *Association Between Proton Pump Inhibitors and the Risk of Hepatocellular Carcinoma*, 48 Alimentary Pharmacology & Therapeutics 4, 460-68 (2018).

of H_2 blockers within one year of cancer diagnosis and still found an increased odds ratio associated with use of H_2 blockers and hepatocellular carcinoma, a type of liver cancer.

210. A number of other studies have been published over the years showing an increased risk of various cancers associated with use of ranitidine and/or H_2 blockers.[124] These cancers include breast, gastric, pancreatic, and stomach cancer. Additional research reports that ranitidine use was associated with a significant increase in the risk of bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancer.[125]

B. Defendant's Knowledge of the NDMA Risk

211. NDMA has been known to be a probable human carcinogen since the 1970s.[126]

212. In 1980, GSK, the originator of the ranitidine molecule, studied how the long term use of ranitidine could affect and elevate the levels of nitrates in the human stomach thus increasing risk of forming nitrosamines and turn into cancer.

213. As early as 1981, two years before Zantac entered the market, research showed elevated rates of NDMA, when properly tested.[127] This was known to GSK and should have been known by each Brand Manufacturer prior to their manufacturing, marketing, labeling, packaging,

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[124] Mathes *et al*., *supra* n.120; *see also* Jeong Soo Ahn *et al*., *Acid Suppressive Drugs and Gastric Cancer: A Meta-analysis of Observational Studies*, 19 World J. Gastroenterology 16, 2560 (2013); Shih-Wei Lai *et al*., *Use of Proton Pump Inhibitors Correlates with Increased Risk of Pancreatic Cancer: A Case-control Study in Taiwan*, 46 Kuwait Med J. 1, 44-48 (2014); Poulsen *et al*., *Proton Pump Inhibitors and Risk of Gastric Cancer – A Population Based Cohort Study*, 100 Brit. J. Cancer 1503-07 (2009); E Wennerström, *Acid-suppressing Therapies and Subsite-specific Risk of Stomach Cancer*, 116 Brit. J. Cancer 9, 1234-38 (2017).

[125] Richard H. Adamson & Bruce A. Chabne, *The Finding of N-Nitrosodimethylamine in Common Medicines,* The Oncologist, June 2020; 25(6): 460-62, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7288647/.

[126] *See EPA Technical Fact Sheet*, *supra* n.16; Int'l Agency for Research on Cancer (IARC) *Summaries & Evaluations, N-NITROSODIMETHYLAMINE* (1978), http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html.

[127] *See supra* ¶¶142, 143, 157, 158 and 167 (discussing de Flora research).

handling, distribution, and/or sale of ranitidine as the information was available in medical literature.

214. In 1981, GSK published a study focusing on the metabolites of ranitidine in urine using liquid chromatography.[128] Many metabolites were listed, though there is no indication that the study looked for NDMA.

215. Indeed, also in 1981, Dr. de Flora published a note discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites—a substance commonly found in food and in the body.[129] GSK was aware of this study because GSK specifically responded to the note and attempted to discredit it. Brand Manufacturers knew or should have known about this scientific exchange as it was published in a popular scientific journal. Brand Manufacturers were obligated to investigate this issue properly. None did.

216. In April 1982, GSK performed a study [redacted]

217. By 1983, Dr. de Flora published complete findings as to formation of genotoxic derivatives from nitrate and ranitidine and expressed concerns as to long term use of ranitidine without precautionary measures.

[128] Carey, *et al*., *Determination of Ranitidine and Its Metabolites in Human Urine by Reversed-phase Ion-pair High-performance Liquid Chromatography*, 255 J. Chromatography B: Biomedical Sci. & Appl. 1, 161-68 (1981).

[129] De Flora, *supra* n.73.

218. [redacted][130]

219. In 1986, GSK extended the market and sale of ranitidine for maintenance therapy.

220. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds, GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[131] That study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). But the study was flawed. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Not only is that approach not accurate, but GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." Without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. The inadequacy of that test was knowable in light of its scientific publication in 1987.

221. All of this was known or available to Pfizer before 2000 when Pfizer acquired Warner-Lambert and took over control of the NDA for Zantac in the United States.

222. Pfizer either knew or should have known about the inadequacy of GSK's studies, the impact and cautionary instructions of independent studies, and should have, through due diligence and/or their own independent testing, investigated the issue properly and/or took action to protect consumers from the NDMA risks in their products. None did.

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[130] GSKZAN0000369313, [redacted]

[131] Thomas *et al.*, *supra* n.94.

C. The Federal Regulatory Landscape

223. Plaintiffs reference federal law herein not in any attempt to enforce it, but only to demonstrate that their state-law claims do not impose any additional obligations on Pfizer, beyond what is already required of them under federal law.

1. Federal Law Required Pfizer To Notify the FDA About the Presence of NDMA In Ranitidine-Containing Products

224. During the time that any Pfizer manufactured and sold Ranitidine-Containing Products in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA. Pfizer failed to report these risks to the FDA.

225. Pfizer concealed the ranitidine–NDMA link from ordinary consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like ranitidine to the agency's attention.

226. Manufacturers of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to 21 C.F.R. §314.81(b)(2):

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

227. Title 21 C.F.R. §314.81(b)(2)(v) provides that the manufacturer's annual report must also contain:

> Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (*e.g.*, mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product.

228. Pfizer ignored these regulations and, disregarding the scientific evidence available to it regarding the presence of NDMA in their products and the risks associated with NDMA, did not report to the FDA significant new information affecting the safety or labeling of Ranitidine-Containing Products.

229. Knowledge regarding the risk of NDMA in ranitidine was sufficiently available in the publicly available scientific literature such that any manufacturer, consistent with its heightened obligations to ensure the safety of its products, also should have known about the potential NDMA risks associated with ranitidine consumption.

230. Pfizer never conducted or provided the relevant studies to the FDA, nor did they present the FDA with a proposed disclosure noting the various ways that ranitidine transforms into NDMA. Accordingly, because Pfizer never properly disclosed the risks to the FDA, they never proposed any labeling or storage / transportation guidelines that would have addressed this risk. Thus, the FDA was never able to reject any proposed warning or proposal for storage/transport.

231. When the FDA eventually learned about the NDMA risks posed by Ranitidine-Containing Products, it ordered manufacturers to voluntarily remove the products from the market.

2. Good Manufacturing Practices

232. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with "Current Good Manufacturing Practices" ("CGMPs") to ensure they meet safety, quality, purity, identity, and strength standards.[132]

233. Title 21 C.F.R. §210.1(a) states that the CGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the

[132] 21 U.S.C. §351(a)(2)(B).

requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

234. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Pfizer had a duty and were obligated to properly store, handle, and warehouse ranitidine.

235. Testing conducted by the FDA confirms that under accelerated conditions the elevated temperatures can lead to the presence of NDMA in the drug product.[133] FDA has also concluded that NDMA can increase in ranitidine under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in Ranitidine-Containing Products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw Ranitidine-Containing Products altogether.

236. Nothing prevented Pfizer from, on their own, taking actions to prevent accumulation of NDMA in Ranitidine-Containing Products by ensuring that ranitidine was not exposed to heat or moisture over long periods.

[133] Woodcock Letter, *supra* 76.

V. PLAINTIFFS' PURCHASES OF RANITIDINE-CONTAINING PRODUCTS

237. Plaintiffs purchased Ranitidine-Containing Products at various times as part of their treatment for gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.

238. Plaintiffs purchased Ranitidine-Containing Products designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Pfizer. Those products, unbeknownst to Plaintiffs, transformed into dangerous levels of NDMA.

239. Based on prevailing scientific evidence, exposure to NDMA caused by consuming Pfizer's Ranitidine-Containing Products causes cancer in humans, including serious and potentially fatal "Subject Cancers" (bladder, colorectal/intestinal, esophageal, gastric, liver, lung, pancreatic, and prostate cancers.)

240. Upon information and belief, Plaintiffs' physicians would not have prescribed and/or recommended Ranitidine-Containing Products to Plaintiffs, would have changed the way in which they treated Plaintiffs' relevant conditions, changed the way they warned Plaintiffs about the signs and symptoms of serious adverse effects of Ranitidine-Containing Products, and discussed with Plaintiffs the true risks of cancer, had Pfizer provided said physicians with an appropriate and adequate warning regarding the risks associated with the use of Ranitidine-Containing Products.

241. Upon information and belief, Plaintiffs' physicians were unaware of the increased risk of multiple types of cancer associated with the use of Ranitidine-Containing Products due to ranitidine's transformation into NDMA and, if they had been informed, would have used and prescribed alternative therapies to Plaintiffs.

242. Plaintiffs would not have purchased Ranitidine-Containing Products had Plaintiffs known of or been fully and adequately informed by Pfizer of the true increased risks and serious dangers of taking the drugs.

VI. EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

A. Discovery-Rule Tolling

243. Within the period of any applicable statutes of limitation, Plaintiffs and members of the proposed Classes could not have discovered through the exercise of reasonable diligence that Pfizer was not disclosing the high levels of the carcinogen, NDMA, in Ranitidine-Containing Products, including Zantac.

244. Plaintiffs and the other Class members did not discover, and did not know of, facts that would have caused a reasonable person to suspect that Pfizer did not disclose the high levels of NDMA in Ranitidine-Containing Products, including Zantac. The information linking ranitidine to NDMA was contained exclusively in articles published in scientific journals and intended for the scientific audience. Plaintiffs and Class members did not have access to these scientific articles because they were behind a paywall. And even if the articles had been more widely available, the significance of the information in these highly technical articles would not have been apparent to Plaintiffs or Class members.

245. Plaintiffs and Class members could not have reasonably discovered the true extent of Pfizer's deception with regard to the safety of Ranitidine-Containing Products until Valisure filed its citizen petition disclosing the extremely high levels of NDMA in Ranitidine-Containing Products, including Zantac.

246. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule.

B. Fraudulent-Concealment Tolling

247. All applicable statutes of limitation have also been tolled by Pfizer's fraudulent concealment of the fact that the ranitidine in Ranitidine-Containing Products, including Zantac, produces high levels of the carcinogen NDMA when ingested.

248. Instead of disclosing the link between ranitidine and the carcinogen, NDMA, Pfizer continued to manufacture and sell Ranitidine-Containing Products without disclosing this information on the drug's label or anywhere else.

C. Estoppel

249. Pfizer were under a continuous duty to disclose to Plaintiffs and the other Class members the risk of NDMA exposure associated with Ranitidine-Containing Products, including Zantac.

250. Pfizer knowingly, affirmatively, and actively concealed or recklessly disregarded the true risks of NDMA exposure associated with Ranitidine-Containing Products, including Zantac, and never updated the drug's label to disclose this risk.

251. Based on the foregoing, Pfizer are estopped from relying on any statutes of limitations in defense of this action.

VII. THE STATE LAW CLAIMS

A. Class Allegations

1. Class Definition

252. Plaintiffs bring this action in their individual capacities and on behalf of their respective State Classes (described below), pursuant to Federal Rules of Civil Procedure 23(a), (b)(2)-(3), and/or (c)(4).

Pfizer

253. Plaintiffs identified in the table below bring claims against Defendant Pfizer on behalf of themselves and their respective State Pfizer OTC Economic Loss Class, each of which is defined as "All individuals who purchased, for personal, family, or household use, Pfizer's OTC Ranitidine-Containing Products while a resident of [State]":

Plaintiff Name	**State(s) of Residence**
Andy Green Jr.	Arkansas
Golbenaz Bakhtiar	California
Richard Obrien	California
Virginia Aragon	California
Jeffrey Pisano	Colorado
Angel Cordero	Connecticut
Gustavo Velasquez	Florida
Joshua Winans	Florida
Ricardo Moròn	Florida
Kathy Jeffries	Florida; Georgia
Janet Asbury	Kentucky
Randy Jones	Louisiana
Alberta Griffin	Maryland
Nicholas Hazlett	Maryland
Jerry Hunt	Michigan
Kenneth Hix	Michigan
Lakisha Wilson	Michigan
Donald Northrup	Minnesota
Roy Armstrong	Minnesota

John Scholl	Minnesota; North Dakota
Beverly Crosby	Mississippi
John Rachal	Mississippi
Dennis Robbins	North Carolina
Gaylord Stauffer	Nebraska
Dan Zhovtis	New York
Mary McCullen	New York
Chris Troyan	Ohio
Michael Galloway	Ohio, Florida
Jonathan Ferguson	Nevada, Oregon; Washington
Gloria Colon	Puerto Rico
Sonia Diaz	Puerto Rico
Dale Hunter	Tennessee
Marianella Villanueva	Texas
Ronda Lockett	Texas, Missouri
Sylvia Yoshida	Texas
Tammy Smith	Texas, Louisiana, Missouri
Earlene Green	Washington
Steve Fischer	Washington
Wendy Quezaire	Wisconsin
Ida Adams	West Virginia; Maryland
Charles Longfield	Wyoming, Maryland

2. Federal Rule of Civil Procedure 23 Requirements

254. Each of the proposed State Classes meets the requirements of Federal Rules of Civil Procedure 23(a), (b)(2)-(3) and/or (c)(4).

255. Numerosity. The members of each class are so numerous that joinder is impracticable. Zantac has for decades been one of the most popular medications for relief of heartburn, acid reflux, and similar conditions and, thus, it is reasonable to infer that each State Class includes thousands if not millions of members who are geographically dispersed throughout the country and/or throughout each respective State.

256. Typicality. Plaintiffs' claims are typical of the claims of putative Class members in that Plaintiffs' claims arise out of the same common course of conduct that gives rise to the claims of the other State Class members. Each Plaintiff, like each State Class member, paid money to purchase prescription and/or OTC Zantac which are not safe for human consumption and, thus, Plaintiffs, like each Class member, suffered out-of-pocket losses. Plaintiffs, like each State Class member, were injured through Pfizer's common course of misconduct, and Plaintiffs are advancing the same legal theories on behalf of themselves and the Class members.

257. Adequacy. Plaintiffs will fairly and adequately protect the interests of the State Class members. Plaintiffs' interests and the interests of all other members of each respective State Class are identical and not antagonistic. Plaintiffs intend to vigorously prosecute this case and will fairly and adequately protect the State Class members' interests. Plaintiffs have retained counsel who are competent and experienced in litigating class actions, including litigation of this kind.

258. Commonality and Predominance. There are numerous questions of law and fact common to the State Classes, and these common questions predominate over any issues affecting only individual State Class members. Questions common to the State Classes include, but are not limited to, the following:

(a) whether Zantac contains, or is likely to contain, unacceptable levels of NDMA;

(b) whether Pfizer knew or should have known that Zantac contains, or is likely to contain, unacceptable levels of NDMA;

(c) whether Pfizer knew or should have known that consumption of Zantac increases the risk of developing cancer;

(d) whether Pfizer acted to conceal the fact that Zantac exposes users to unacceptable quantities of NDMA;

(e) whether Pfizer acted to conceal the fact that Zantac contains, or are likely to contain, unacceptable levels of NDMA and increase the risk of developing cancer;

(f) whether Pfizer's labeling, packaging, marketing, advertising, or promotion of Zantac misrepresented or omitted the safety of Ranitidine-Containing Products and/or Zantac, or failed to disclose that Zantac contains and continues to produce high levels of the carcinogen NDMA;

(g) whether Pfizer's labeling, packaging, marketing, advertising, or promotion of Zantac misrepresented or omitted the safety of Zantac, or failed to disclose that consumption of Ranitidine-Containing Products increases the risk of developing cancer;

(h) whether Pfizer's labeling, packaging, marketing, advertising, or promotion of Zantac misrepresented or omitted the safety of Zantac, when used beyond the expiration dates;

(i) whether Pfizer's conduct was knowing or willful;

(j) whether Pfizer's conduct violated state consumer-protection statutes;

(k) whether Pfizer breached implied warranties;

(l) whether Pfizer have been unjustly enriched;

(m) whether Plaintiffs and the State Class members are entitled to recover damages and the appropriate measure of those damages;

(n) the appropriate measure of disgorgement; and

(o) the type and format of injunctive relief that is appropriate.

259. Superiority. A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The quintessential purpose of the class action mechanism is to permit litigation against wrongdoers even when damages to an individual plaintiff may not be sufficient to justify individual litigation. Here, the damages suffered by Plaintiffs and the State Class are relatively small compared to the burden and expense required to individually litigate their claims against Pfizer, and thus, individual litigation to redress Pfizer's wrongful conduct would be impracticable. Individual litigation by each State Class member would also strain the court system, create the potential for inconsistent or contradictory judgments, and increase the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

260. Injunctive and Declaratory Relief. Class certification is also appropriate under Rule 23(b)(2) because Pfizer acted and refused to act on grounds generally applicable to the State Class as a whole, such that final injunctive relief is appropriate with respect to the State Class as a whole.

261. Plaintiffs reserve the right to seek certification under Rule 23(c)(4) of common questions related to Pfizer's knowledge, conduct, products, and duties.

B. Additional Factual Allegations

1. Pfizer's Misrepresentations or Omissions of Material Fact in the Labeling and Packaging of OTC Ranitidine-Containing Products

262. Pfizer increased OTC Ranitidine–Containing Product demand through a fundamental and uniform message, parlayed through a multi-media campaign that OTC Zantac is safe, it can be used frequently, long-term, with high-nitrate and -nitrite foods, and poses no serious

health risks such as those associated with the consumption of NDMA—a known human carcinogen.

263. Examples of this campaign include a series of television, print, radio, and internet ads for OTC Zantac throughout the United States and to consumers that uniformly omitted the material safety risks that the products contained NDMA, that ranitidine was instable, that NDMA content could increase through the lapse of time and when exposed to heat or humidity, and that it should not be used in connection with high-nitrate or -nitrite foods.

264. At the point of sale, Pfizer sold Zantac packaged and labeled with misleading information and material omissions.

a. Misrepresentations or Omissions of Material Fact on the Labels

265. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded—
>
> (a) **FALSE OR MISLEADING LABEL**
>
> (1) If its labeling is false or misleading in any particular.

(emphasis in original).

266. Pfizer was required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[134] and conform to requirements governing the appearance of the label.[135]

[134] 21 C.F.R. §201.5.

[135] *Id.* §201.15.

267. "Labeling" encompasses all written, printed, or graphic material accompanying the drug or device,[136] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

268. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[137]

269. Pfizer were also responsible for conducting stability testing, which must be "designed to assess the stability characteristics of drug products."[138] Manufacturers must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."[139]

270. The purpose of stability testing is, in part, to determine the "appropriate storage conditions and expiration dates."[140] And expiration dates, in turn, must be set to "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of

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[136] *Id.*; 65 Fed. Reg. 14286 (Mar. 16, 2000).

[137] *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).

[138] 21 C.F.R. §211.166(a).

[139] *Id.*

[140] *Id.*

use."[141] An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies listed in §211.166."[142]

271. Pfizer must conduct its own tests to determine and set accurate retest or expiration dates.

272. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the "stability of a specific active ingredient." Instead, a compliant expiration date must account for multiple factors, including "the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use."[143]

273. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: "Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined."[144]

274. After a drug is approved, a manufacturer can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§ 314.70 and 314.71.[145]

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[141] *Id.* §211.137(a).

[142] *Id.* §211.137(b).

[143] 43 Fed. Reg. 45059 (Sept. 29, 1978).

[144] 21 C.F.R. §211.166(b).

[145] *See id.* §314.97(a) (requiring generics to comply with §§314.70, 314.71).

275. Some of the requirements in those regulations require a brand manufacturer of an approved drug to obtain FDA approval before implementing a label change.[146]

276. But the FDA has long recognized a CBE supplement that permits a manufacturer to make immediate changes, subject to the FDA's post-change review.[147]

277. A manufacturer of an approved drug can use the CBE supplement to immediately make an "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess."[148] "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described."[149]

278. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date—which must "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use"[150]—or to ensure that the drug is shipped and stored under appropriate conditions.

279. A manufacturer of an approved drug can also use the CBE supplement to make changes "in the labeling to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter"; "add or strengthen an instruction about dosage and administration that is intended to increase the

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146 *Id.* §314.70(b).

147 *Id.* §314.70(c)(3), (c)(6).

148 *Id.* §314.70(c)(6)(i).

149 65 Fed. Reg. 83042 (Dec. 29, 2000).

150 21 C.F.R. §211.137(a).

safe use of the drug product"; and "delete false, misleading, or unsupported indications for use or claims for effectiveness."[151]

280. A manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes "[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form."[152]

281. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the NDA."[153]

282. At no time did Pfizer attempt to include a warning on the labels for ranitidine-containing products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

283. At no time did Pfizer attempt to change its label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that ranitidine-containing products would not break down into NDMA prior to human consumption.

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[151] *Id.* §314.70(c)(6)(iii)(A), (C), (D).

[152] *Id.* §314.70 (d)(2)(ix).

[153] *Id.* §314.70 (d)(2)(vi); *see also id.* §314.70(d)(2)(vii), (x).

284. Based on the public scientific information, the Pfizer knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

285. At no time did Pfizer change its label to shorten the expiration date. Pfizer had the ability to unilaterally make such label changes without prior FDA approval pursuant to the CBE regulation. Had Pfizer attempted such label changes, the FDA would not have rejected them.

286. Because they failed to include appropriate expiration dates on their products, Pfizer made false statements in the labeling of their products.

287. Because they failed to include a warning on the labels for ranitidine-containing products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months, Brand Name OTC Manufacturer Pfizer made false statements in the labeling of their products.


Regular Strength
Zantac
Ranitidine Tablets 75 mg / Acid Reducer
75
Regular Strength
Zantac
Ranitidine Tablets 75 mg / Acid Reducer
75
PREVENTS & RELIEVES
HEARTBURN associated with
acid indigestion and sour stomach
80 TABLETS
(80 DOSES)
Zantac
75
80 TABLETS
(80 DOSES)
Zantac
75
80 TABLETS
(80 DOSES)
LOT
EXP


MAXIMUM STRENGTH
Zantac
Ranitidine Tablets 150 mg/Acid Reducer
150
VALUE SIZE 90 TABLETS
VALUE SIZE 90 TABLETS
MAXIMUM STRENGTH
Zantac
Ranitidine Tablets 150 mg/Acid Reducer
150
PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach
90 TABLETS (90 DOSES)
SANOFI
MAXIMUM STRENGTH
Zantac
150
90 TABLETS (90 DOSES)

288. Because they failed to package their products in appropriate container sizes, Pfizer made false statements in the packaging of their products.

289. Pfizer's conduct, as described above, was reckless. Pfizer regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of their products. Pfizer have made conscious decisions not to change the containers for their ranitidine-containing products. Pfizer's reckless conduct therefore warrants an award of punitive damages.

VIII. CAUSES OF ACTION

290. For the purposes of the subsequent causes of action against Defendant Pfizer, Plaintiffs are incorporating the following allegations by reference: paragraphs 2-3 (corporate information); 56-40 (jurisdiction and venue); 61-85 (development of brand Zantac); 86-130 (knowledge that NDMA is carcinogenic); 131-151 (discovery by regulatory agencies that ranitidine contained NDMA); 152-155 (transformation of ranitidine into NDMA); 156-183 (knowledge that ranitidine had the potential to transform into NDMA); 184-190 (NDMA formation in 24 of the human body); 191-203 (NDMA formation by exposure to heat, moisture and/or time); 204-210 (link between ranitidine exposure and cancer); 232-236 (compliance with current Good Manufacturing Practices); 262-289 (misrepresentations or omissions of material fact in labeling and packaging); 237-242 (Plaintiffs' purchases of Rantidine-Containing Products) and 243-251 (equitable tolling).

291. Plaintiffs identified in the table below bring claims against Defendant Pfizer on behalf of themselves and their respective State Classes under the laws of their respective states. Each Plaintiff incorporates by reference the allegations specific to them from Section II.C., *supra*, into their respective claims below:

Plaintiff Name	**State(s) of Residence**
Andy Green Jr.	Arkansas
Golbenaz Bakhtiar	California
Richard Obrien	California
Virginia Aragon	California
Jeffrey Pisano	Colorado
Angel Cordero	Connecticut
Gustavo Velasquez	Florida
Joshua Winans	Florida
Ricardo Moròn	Florida
Kathy Jeffries	Florida; Georgia
Janet Asbury	Kentucky
Randy Jones	Louisiana
Alberta Griffin	Maryland
Nicholas Hazlett	Maryland
Jerry Hunt	Michigan
Kenneth Hix	Michigan
Lakisha Wilson	Michigan
Donald Northrup	Minnesota
Roy Armstrong	Minnesota
John Scholl	Minnesota; North Dakota
Beverly Crosby	Mississippi
John Rachal	Mississippi
Dennis Robbins	North Carolina
Gaylord Stauffer	Nebraska
Dan Zhovtis	New York
Mary McCullen	New York
Chris Troyan	Ohio
Michael Galloway	Ohio, Florida
Jonathan Ferguson	Nevada, Oregon; Washington

Gloria Colon	Puerto Rico
Sonia Diaz	Puerto Rico
Dale Hunter	Tennessee
Marianella Villanueva	Texas
Ronda Lockett	Texas, Missouri
Sylvia Yoshida	Texas
Tammy Smith	Texas, Louisiana, Missouri
Steve Fischer	Washington
Earlene Green	Washington
Wendy Quezaire	Wisconsin
Ida Adams	West Virginia; Maryland
Charles Longfield	Wyoming, Maryland

1. Causes of Action on Behalf of the Arkansas-Pfizer Classes

COUNT 1
Violation of the Arkansas Deceptive Trade Practices Act
(Ark. Code Ann. §4-88-101, *et seq.*)
(Against Pfizer)

292. Arkansas Class Representative Andy Green Jr. incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

293. This cause of action is brought on behalf of the Arkansas-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

294. Defendant, Plaintiff, and the Class members are "[p]erson[s]" within the meaning of Ark. Code Ann. §4-88-102(5).

295. The Ranitidine-Containing Products are "[g]oods" within the meaning of Ark. Code Ann. §4-88-102(4).

296. The Arkansas Deceptive Trade Practices Act ("Arkansas DTPA") prohibits "[d]eceptive and unconscionable trade practices." Ark. Code Ann. §4-88-107(a).

297. The Arkansas DTPA makes unlawful specific acts, including:

(a) "[k]nowingly making a false representation as to the characteristics, ingredients, uses, benefits, alterations, source, sponsorship, approval, or certification of goods or services or as to whether goods are original or new or of a particular standard, quality, grade, style, or model" (Ark. Code Ann. §4-88-107(a)(1));

(b) "[a]dvertising the goods or services with the intent not to sell them as advertised" (Ark. Code Ann. §4-88-107(a)(3)); and

(c) "[e]ngaging in any other unconscionable, false, or deceptive act or practice in business, commerce, or trade" (Ark. Code Ann. §4-88-107(a)(10)).

298. The Arkansas DTPA also prohibits the following when utilized in connection with the sale or advertisement of any goods: "(1) The act, use, or employment by any person of any deception, fraud, or false pretense; [or] (2) [t]he concealment, suppression, or omission of any material fact with intent that others rely upon the concealment, suppression, or omission . . . ." Ark. Code Ann. §4-88-108(a).

299. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Arkansas DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

300. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Arkansas DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products

remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

301. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Arkansas DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

302. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Arkansas DTPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

303. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

304. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

305. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

306. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

307. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiff and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

308. Plaintiff and the Class members relied on Defendant's misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendant's misrepresentations, omissions, and concealments were made.

309. Plaintiff and the Class members were aggrieved by Defendant's violations of Arkansas DTPA because they suffered ascertainable loss and actual damages as a direct and

proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

310. Specifically, Plaintiff and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiff and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

311. Defendant's violations present a continuing risk to Plaintiff and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

312. As a result of Defendant's violations of the Arkansas DTPA, as alleged herein, Plaintiff and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Arkansas DTPA.

COUNT 2
Breach of Implied Warranty
(Ark. Code Ann. §4-2-314)
(Against Pfizer)

313. Arkansas Class Representative Andy Green Jr. incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

314. This cause of action is brought on behalf of the Arkansas-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

315. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to Arkansas Class Representatives and members of the Arkansas Class and was in the business of selling such products.

316. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

317. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

318. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

319. Defendant had reason to know Plaintiff and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiff and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

320. Plaintiff and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

321. Plaintiff and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiff and each member of the Class, on the other hand.

322. Further, Plaintiff and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

323. Plaintiff and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiff and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

324. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiff and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 3
Unjust Enrichment
(Arkansas Law)
(Against Pfizer)

325. Arkansas Class Representative Andy Green Jr. incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

326. This cause of action is brought on behalf of the Arkansas-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

327. Plaintiff and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

328. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiff and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiff and Class members conferred a financial benefit on Pfizer but did not receive their expected benefit therefrom.

329. Defendant readily accepted and retained these benefits from Plaintiff and Class members and knowingly benefitted from its unjust conduct – at Plaintiff's and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

330. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiff and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

331. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiff and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

332. There is no valid, legal, and binding contract governing this dispute.

333. Plaintiff and Class members do not have an adequate remedy at law.

2. Causes of Action on Behalf of the California-Pfizer Classes

COUNT 4
Violation of the California Unfair Competition Law
(Cal. Bus. & Prof. Code §17200, *et seq.*)
(Against Pfizer)

334. California Class Representatives Golbenaz Bakhtiar, Richard O'brien, and Virginia Aragon incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

335. This cause of action is brought on behalf of the California-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

336. Defendant, Plaintiffs, and the Class members are "persons" within the meaning of Cal. Bus. & Prof. Code §17201.

337. Cal. Bus. & Prof. Code §17200 ("California UCL") prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising."

338. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the California UCL by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their

intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

339. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the California UCL by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

340. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the California UCL by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

341. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the California UCL. These acts also constitute "fraudulent" business acts and practices under the California UCL in that Defendant's conduct is false, misleading, and has a tendency to deceive the Class and the general public.

342. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

343. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

344. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

345. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

346. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

347. Moreover, Defendant engaged in "unlawful" business acts or practices by violating both federal and California laws, including: the federal RICO statute, 18 U.S.C. §1962(c)-(d); adulteration and misbranding provisions under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§331(a), (c), (g), 351(a)(2)(B), (b), (d), 352(a)(1), (c), (e)(1)(A)(ii), (f)-(g), (i)(2)-(3), (j),

(n), (p); Good Manufacturing Practices, 21 C.F.R. 210.1(a), 211.142(b); adulteration and misbranding provisions under the Sherman Food, Drug, and Cosmetic Laws, Cal. Health & Safety Code §§111260, 111280, 111290, 111295, 111305, 111330, 111345, 111355(a)(3), 111360(b), 111375, 111380, 111395(a)-(b), 111400, 111440, 111445, 111450; the Consumer Legal Remedies Act, Cal. Civ. Code §1750; and the California FAL, Cal. Bus. & Prof. Code §17500, as alleged herein.

348. Defendant's conduct also consitutes "unfair" business acts or practies. Under the balancing test, the determination of whether a business practice is "unfair" involves examining the practice's impact on its alleged victim, balanced against the reasons, justifications, and motives of the alleged wrongdoer.

349. Additionally, Defendant's conduct was "unfair" under the tethering test, in that it violated the federal RICO statute, 18 U.S.C. §1962(c)-(d); adulteration and misbranding provisions under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§331(a), (c), (g), 351(a)(2)(B), (b), (d), 352(a)(1), (c), (e)(1)(A)(ii), (f)-(g), (i)(2)-(3), (j), (n), (p); Good Manufacturing Practices, 21 C.F.R. 210.1(a), 211.142(b); adulteration and misbranding provisions under the Sherman Food, Drug, and Cosmetic Laws, Cal. Health & Safety Code §§111260, 111280, 111290, 111295, 111305, 111330, 111345, 111355(a)(3), 111360(b), 111375, 111380, 111395(a)-(b), 111400, 111440, 111445, 111450; the Consumer Legal Remedies Act, *see* Cal. Civ. Code §1760; and the California FAL, Cal. Bus. & Prof. Code §17500, which reflect the United States' and California's policy of protecting consumers against unfair and deceptive business practices and adulterated and misbranded drugs.

350. Plaintiffs and the Class members were aggrieved by Defendant's violations of the California UCL because they suffered ascertainable loss and actual damages as a direct and

proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

351. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

352. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

353. Pursuant to Cal. Bus. & Prof. Code §§17200 and 17203, Plaintiffs and the Class members seek an order providing restitution relating to the above-described unfair business acts or practices, and injunctive and declaratory relief as may be appropriate.

COUNT 5
Violation of the California False Advertising Law
(Cal. Bus. & Prof. Code §17500, *et seq.*)
(Against Pfizer)

354. California Class Representatives Golbenaz Bakhtiar, Richard O'brien, and Virginia Aragon incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

355. This cause of action is brought on behalf of the California-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

356. Defendant, Plaintiffs, and the Class members are "persons" within the meaning of Cal. Bus. & Prof. Code §17506.

357. The California False Advertising Law ("California FAL") prohibits "any person, . . . corporation . . . or any employee thereof with intent directly or indirectly to dispose of real or personal property . . . or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated . . . before the public in this state or from this state before the public in any state, in any newspaper or other publication, or any advertising device, . . . or in any other manner or means whatever, including over the internet, any statement . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading." Cal. Bus. & Prof. Code §17500.

358. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the California FAL by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

359. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the California FAL by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

360. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the California FAL by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-

Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

361. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the California FAL, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

362. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

363. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

364. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

365. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

366. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

367. Plaintiffs and the Class members were aggrieved by Defendant's violations of the California FAL because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

368. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

369. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

370. As a result of Defendant's violations of the California FAL, as alleged herein, Plaintiffs and the Class members seek an order providing restitution and disgorgement of all profits relating to the above-described business acts or practices, and other appropriate relief, including injunctive and declaratory relief as may be appropriate under the California FAL.

COUNT 6
Violation of the California Consumers Legal Remedies Act
(Cal. Civ. Code §1750, *et seq.*)
(Against Pfizer)

371. California Class Representatives Golbenaz Bakhtiar, Richard O'brien, and Virginia Aragon incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

372. This cause of action is brought on behalf of the California-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

373. Defendant, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Cal. Civ. Code §1761(c).

374. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Cal. Civ. Code §1761(d).

375. The Ranitidine-Containing Products are "[g]oods" within the meaning of Cal. Civ. Code §1761(a).

376. The California Consumers Legal Remedies Act ("California CLRA") prohibits "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person

in a transaction intended to result or that results in the sale or lease of goods or services to any consumer." Cal. Civ. Code §1770(a).

377. The California CLRA makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Cal. Civ. Code §1770(a)(5));

(b) "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" (Cal. Civ. Code §1770(a)(7));

(c) "[a]dvertising goods or services with intent not to sell them as advertised" (Cal. Civ. Code §1770(a)(9)); and

(d) "[r]epresenting that the subject of a transaction has been supplied in accordance with a previous representation when it has not" (Cal. Civ. Code §1770(a)(16)).

378. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the California CLRA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

379. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the California CLRA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

380. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the California CLRA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

381. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the California CLRA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

382. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

383. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

384. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of

Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

385. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

386. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

387. Plaintiffs and the Class members were aggrieved by Defendant's violations of the California CLRA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products, as set forth above.

388. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices

alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

389. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

390. Defendant was provided notice of the issues raised in this Count and this Complaint by the FDA investigations, the numerous complaints filed against it, and the many individual notice letters sent by various Plaintiff within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to Cal. Civ. Code §1782 to Defendant. Because Defendant failed to adequately remedy its unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiff and the Class members are entitled.

391. Pursuant to Cal. Civ. Code §1780(a), Plaintiff and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding damages and any other just and proper relief available under the California CLRA. Under Cal. Civ. Code §1780(b), Plaintiffs seek an additional award against Defendant of up to $5,000 for each Class member who qualifies as a "senior citizen" or "disabled person" under the California CLRA. Defendant knew or should have known that its conduct was directed to one or more Class members who are senior citizens or disabled persons. Defendant's conduct caused one or more of these senior citizens or disabled persons to suffer a substantial loss of property set aside for retirement or for personal or family care and maintenance, or assets essential to the health or welfare of the senior citizen or disabled person. One or more Class members who are senior citizens or disabled persons are substantially more vulnerable to Defendant's conduct because of age, poor health or infirmity,

impaired understanding, restricted mobility, or disability, and each of them suffered substantial economic damage resulting from Defendant's conduct.

COUNT 7
Breach of Implied Warranty
(Cal. Com. Code §2314)
(Against Pfizer)

392. California Class Representatives Golbenaz Bakhtiar, Richard O'brien, and Virginia Aragon incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

393. This cause of action is brought on behalf of the California-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

394. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to the California Class Representatives and members of the California Class and was in the business of selling such products.

395. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

396. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

397. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

398. Defendant had reason to know Plaintiffs and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiffs and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

399. Plaintiffs and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

400. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

401. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

402. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiffs and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

403. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and

punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 8
Unjust Enrichment or Quasi-Contract
(California Law)
(Against Pfizer)

404. California Class Representatives Golbenaz Bakhtiar, Richard O'brien, and Virginia Aragon incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

405. This cause of action is brought on behalf of the California-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

406. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

407. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

408. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and knowingly benefitted from its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of

NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

409. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

410. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

411. Plaintiffs and Class members do not have an adequate remedy at law.

3. Causes of Action on Behalf of the Colorado-Pfizer Classes

COUNT 9
Violation of the Colorado Consumer Protection Act
(Colo. Rev. Stat. Ann. §6-1-101, *et seq.*)
(Against Pfizer)

412. Colorado Class Representative Jeffrey Pisano incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

413. This cause of action is brought on behalf of the Colorado-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

414. Defendant, Plaintiff, and the Class members are "[p]erson[s]" within the meaning of Colo. Rev. Stat. Ann. §6-1-102(6).

415. The Colorado Consumer Protection Act ("Colorado CPA") prohibits unfair, unconscionable, and deceptive acts or practices "in the course of the person's business, vocation, or occupation." Colo. Rev. Stat. Ann. §6-1-105(1).

416. The Colorado CPA makes unlawful specific acts, including:

(a) "[e]ither knowingly or recklessly mak[ing] a false representation as to the source, sponsorship, approval, or certification of goods, services, or property" (Colo. Rev. Stat. Ann. §6-1-105(1)(b));

(b) "[r]epresent[ing] that goods, food, services, or property are of a particular standard, quality, or grade, or that goods are of a particular style or model, if he knows or should know that they are of another" (Colo. Rev. Stat. Ann. §6-1-105(1)(g));

(c) "[a]dvertis[ing] goods, services, or property with intent not to sell them as advertised" (Colo. Rev. Stat. Ann. §6-1-105(1)(i));

(d) "[f]ails to disclose material information concerning goods, services, or property which information was known at the time of an advertisement or sale if such failure to disclose such information was intended to induce the consumer to enter into a transaction" (Colo. Rev. Stat. Ann. §6-1-105(1)(u)); and

(e) "[e]ither knowingly or recklessly engage[ing] in any unfair, unconscionable, deceptive, deliberately misleading, false, or fraudulent act or practice" (Colo. Rev. Stat. Ann. §6-1-105(1)(kkk)).

417. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Colorado CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer. Such conduct was bad faith conduct under the Colorado CPA.

418. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Colorado CPA by knowingly and intentionally misrepresenting, omitting, concealing, and

failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

419. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Colorado CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

420. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Colorado CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised;

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce; and

(e) failing to disclose the defective Ranitidine-Containing Products in connection with their sale to the public.

421. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

422. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

423. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

424. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

425. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiff and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

426. Plaintiff and the Class members relied on Defendant's misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendant's misrepresentations, omissions, and concealments were made.

427. Plaintiff and the Class members were aggrieved by Defendant's violations of the Colorado CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

428. Specifically, Plaintiff and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiff and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

429. Defendant's violations present a continuing risk to Plaintiff and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

430. As a result of Defendant's violations of the Colorado CPA, as alleged herein, Plaintiff and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Colorado CPA.

COUNT 10
Unjust Enrichment
(Colorado Law)
(Against Pfizer)

431. Colorado Class Representatives Jeffrey Pisano and Tammy Smith incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

432. This cause of action is brought on behalf of the Colorado-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

433. Plaintiff and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

434. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiff and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiff and Class members suffered a detriment because they purchased worthless medications and did not receive the expected benefit therefrom.

435. Defendant readily accepted and retained these benefits from Plaintiff and Class members and knowingly benefitted from its unjust conduct – at Plaintiff' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which

the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

436. It is unjust and inequitable for the Defendant to retain these benefits without commensurate compensation because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiff and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

437. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiff and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

438. Plaintiff and Class members do not have an adequate remedy at law.

4. Causes of Action on Behalf of the Connecticut Class

COUNT 11
Violation of the Connecticut Unfair Trade Practices Act
(Conn. Gen. Stat. Ann. §42-110a, *et seq.*)
(Against Pfizer)

439. Connecticut Class Representative Angel Cordero incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

440. This cause of action is brought on behalf of the Connecticut-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

441. Defendant, Plaintiff, and the Class members are "[p]erson[s]" within the meaning of Conn. Gen. Stat. Ann. §42-110a(3).

442. Defendant was and is engaged in "[t]rade" or "commerce" within the meaning of Conn. Gen. Stat. Ann. §42-110a(4).

443. The Connecticut Unfair Trade Practices Act ("Connecticut UTPA") prohibits "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. Ann. §42-110b(a).

444. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Connecticut UTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

445. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Connecticut UTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

446. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Connecticut UTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

447. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above,

Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Connecticut UTPA.

448. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

449. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

450. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

451. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

452. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiff and the Class

members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

453. Plaintiff and the Class members were aggrieved by Defendant's violations of the Connecticut UTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

454. Specifically, Plaintiff and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiff and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

455. Defendant's violations present a continuing risk to Plaintiff and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

456. As a result of Defendant's violations of the Connecticut UTPA, as alleged herein, Plaintiff and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Connecticut UTPA.

COUNT 12
Breach of Implied Warranty
(Conn. Gen. Stat. Ann. §42a-2-314)
(Against Pfizer)

457. Connecticut Class Representative Angel Cordero incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

458. This cause of action is brought on behalf of the Connecticut-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

459. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to the Connecticut Class Representative and members of the Connecticut Class and was in the business of selling such products.

460. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

461. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

462. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

463. Defendant had reason to know Plaintiff and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiff and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

464. Plaintiff and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

465. Plaintiff and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiff and each member of the Class, on the other hand.

466. Further, Plaintiff and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

467. Plaintiff and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiff and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

468. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiff and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 13
Unjust Enrichment
(Connecticut Law)
(Against Pfizer)

469. Connecticut Class Representative Angel Cordero incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

470. This cause of action is brought on behalf of the Connecticut-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

471. Plaintiff and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

472. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiff and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiff and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

473. Defendant readily accepted and retained these benefits from Plaintiff and Class members and knowingly benefitted from its unjust conduct – at Plaintiff's and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

474. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the

Ranitidine-Containing Products from Plaintiff and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

475. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiff and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

476. Plaintiff and Class members do not have an adequate remedy at law.

5. Causes of Action on Behalf of the Florida-Pfizer Classes

COUNT 14
Violation of the Florida Deceptive and Unfair Trade Practices Act
(Fla. Stat. Ann. §501.201, *et seq.*)
(Against Pfizer)

477. Florida Class Representatives Gustavo Velasquez, Joshua Winans, Michael Galloway, Ricardo Moròn, and Kathy Jeffries incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

478. This cause of action is brought on behalf of the Florida-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

479. The Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. Ann. §501.204(1).

480. In construing the provisions of the FDUTPA, "due consideration and great weight shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to s. 5(a)(1) of the Federal Trade Commission Act, 15 U.S.C. s. 45(a)(1) as of July 1, 2017." Fla. Stat. Ann. §501.204(2).

481. Plaintiffs and the Class members are "[c]onsumer[s]" and "[i]nterested part[ies] or person[s]" as defined by the FDUTPA. *See* Fla. Stat. Ann. §501.203(6)-(7).

482. Defendant engaged in "[t]rade or commerce" as defined by the FDUTPA. *See* Fla. Stat. Ann. §501.203(8).

483. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the FDUTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

484. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the FDUTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

485. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the FDUTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

486. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the FDUTPA.

487. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

488. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

489. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

490. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

491. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

492. Plaintiffs and the Class members were aggrieved by Defendant's violations of the FDUTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

493. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

494. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

495. As a result of Defendant's violations of the FDUTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the FDUTPA.

COUNT 15
Unjust Enrichment
(Florida Law)
(Against Pfizer)

496. Florida Class Representatives Gustavo Velasquez, Joshua Winans, Michael Galloway, Ricardo Moròn, and Kathy Jeffries incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

497. This cause of action is brought on behalf of the Florida-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

498. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

499. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members suffered an impoverishment because they purchased worthless medications and did not receive the expected benefit therefrom.

500. Defendant voluntarily accepted and retained these benefits from Plaintiffs and Class members and was knowingly enriched by its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

501. It is unjust and inequitable for the Defendant to retain these benefits without paying the value thereof because the benefits were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

502. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

503. There is no express written contract governing this dispute.

504. Plaintiffs and Class members do not have an adequate remedy at law.

6. Causes of Action on Behalf of the Georgia-Pfizer Classes

COUNT 16
Violation of the Georgia Fair Business Practices Act
(Ga. Code Ann. §10-1-390, *et seq.*)
(Against Pfizer)

505. Georgia Class Representative Kathy Jeffries incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

506. This cause of action is brought on behalf of the Georgia-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

507. Defendant, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Ga. Code Ann. §10-1-392(a)(24).

508. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Ga. Code Ann. §10-1-392(a)(6).

509. Defendant was and is engaged in "[t]rade" and "commerce" within the meaning of Ga. Code Ann. §10-1-392(a)(28).

510. The Georgia Fair Business Practices Act ("Georgia FBPA") prohibits "[u]nfair or deceptive acts or practices in the conduct of consumer transactions and consumer acts or practices in trade or commerce." Ga. Code Ann. §10-1-393(a).

511. The Georgia FBPA makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Ga. Code Ann. §10-1-393(b)(5));

(b) "[r]epresenting that goods or services are of a particular standard, quality, or grade or that goods are of a particular style or model, if they are of another" (Ga. Code Ann. §10-1-393(b)(7)); and

(c) "[a]dvertising goods or services with intent not to sell them as advertised" (Ga. Code Ann. §10-1-393(b)(9)).

512. In the course of its business, Defendant, through its agents, employees, and/or subsidiaries, violated the Georgia FBPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

513. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Georgia FBPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

514. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Georgia FBPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

515. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Georgia FBPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

516. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

517. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

518. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

519. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the

inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

520. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

521. Plaintiffs and the Class members reasonably relied on Defendant's misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendant's misrepresentations, omissions, and concealments were made.

522. Plaintiffs and the Class members were aggrieved by Defendant's violations of the Georgia FBPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

523. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

524. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

525. Defendant was provided notice of the issues raised in this Count and this Complaint by the FDA investigations, the numerous complaints filed against it, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to Ga. Code Ann. §10-1-399(b) to Defendant. Because Defendant failed to adequately remedy its unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

526. As a result of Defendant's violations of the Georgia FBPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Georgia FBPA.

COUNT 17
Unjust Enrichment
(Georgia Law)
(Against Pfizer)

527. Georgia Class Representative Kathy Jeffries and incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

528. This cause of action is brought on behalf of the Georgia-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

529. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products, or were otherwise in privity with Defendant through said transaction.

530. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

531. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and knowingly benefitted from its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

532. It is inequitable and unconscionable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

533. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

534. There is no express contract governing this dispute.

535. Plaintiffs and Class members do not have an adequate remedy at law.

7. Causes of Action on Behalf of the Kentucky-Pfizer Classes

COUNT 18
Violation of the Kentucky Consumer Protection Act
(Ky. Rev. Stat. Ann. §367.110, *et seq.*)
(Against Pfizer)

536. Kentucky Class Representative Janet Asbury incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

537. This cause of action is brought on behalf of the Kentucky-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

538. Defendant, Plaintiff, and the Class members are "[p]erson[s]" within the meaning of Ky. Rev. Stat. Ann. §367.110(1).

539. Defendant was and is engaged in "[t]rade" or "commerce" within the meaning of Ky. Rev. Stat. Ann. §367.110(2).

540. The Kentucky Consumer Protection Act ("Kentucky CPA") prohibits "[u]nfair, [unconscionable], false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." Ky. Rev. Stat. Ann. §367.170(1)-(2).

541. In the course of its business, Defendant, through its agents, employees, and/or subsidiaries, violated the Kentucky CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably

dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

542. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Kentucky CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

543. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Kentucky CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

544. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive business practices prohibited by the Kentucky CPA.

545. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

546. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

547. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

548. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

549. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiff and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

550. Plaintiff and the Class members were aggrieved by Defendant's violations of the Kentucky CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

551. Specifically, Plaintiff and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiff and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

552. Defendant's violations present a continuing risk to Plaintiff and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

553. As a result of Defendant's violations of the Kentucky CPA, as alleged herein, Plaintiff and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Kentucky CPA.

COUNT 19
Breach of Implied Warranty
(Ky. Rev. Stat. Ann. §355.2-314)
(Against Pfizer)

554. Kentucky Class Representative Janet Asbury incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

555. This cause of action is brought on behalf of the Kentucky-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

556. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to Kentucky Class Representatives and members of the Kentucy Class and was in the business of selling such products.

557. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used,

including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

558. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

559. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

560. Defendant had reason to know Plaintiff and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products, and knew that Plaintiff and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

561. Plaintiff and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

562. Plaintiff and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiff and each member of the Class, on the other hand.

563. Further, Plaintiff and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

564. Plaintiff and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiff and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

565. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiff and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 20
Unjust Enrichment
(Kentucky Law)
(Against Pfizer)

566. Kentucky Class Representative Janet Asbury incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

567. This cause of action is brought on behalf of the Kentucky-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

568. Plaintiff and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

569. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiff and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe

and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiff and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

570. Defendant readily accepted and retained these benefits from Plaintiff and Class members and knowingly benefitted from its unjust conduct – at Plaintiff's and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

571. It would be inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiff and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

572. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiff and Class members through its unjust and unlawful acts without paying for the value thereof, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

573. Plaintiff and Class members do not have an adequate remedy at law.

8. Causes of Action on Behalf of the Louisiana-Pfizer Classes

COUNT 21
Violation of the Louisiana Unfair Trade Practices and Consumer Protection Law
(La. Stat. Ann. §51:1401, *et seq.*)
(Against Pfizer)

574. Louisiana Class Representatives, Tammy Smith and Randy Jones incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

575. This cause of action is brought on behalf of the Louisiana-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

576. Defendant, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of La. Stat. Ann. §51:1402(8).

577. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of La. Stat. Ann. §51:1402(1).

578. Defendant was and is engaged in "[t]rade" or "commerce" within the meaning of La. Stat. Ann. §51:1402(10).

579. The Louisiana Unfair Trade Practices and Consumer Protection Law ("Louisiana CPL") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." La. Stat. Ann. §51:1405(A).

580. In the course of its business, Defendant, through its agents, employees, and/or subsidiaries, violated the Louisiana CPL by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

581. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Louisiana CPL by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

582. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Louisiana CPL by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

583. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive business practices prohibited by the Louisiana CPL.

584. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

585. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

586. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

587. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

588. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

589. Plaintiffs and the Class members relied on Defendant's misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendant's misrepresentations, omissions, and concealments were made.

590. Plaintiffs and the Class members were aggrieved by Defendant's violations of the Louisiana CPL because they suffered ascertainable loss and actual damages as a direct and

proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

591. Specifically, Plaintiffs and the Class were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiff and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

592. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

593. As a result of Defendant's violations of the Louisiana CPL, as alleged herein, Plaintiffs and the Class members seek an order awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Louisiana CPL.

COUNT 22
Breach of Implied Warranty
(La. Civ. Code Ann. Art. §2520)
(Against Pfizer)

594. Louisiana Class Representatives, Tammy Smith and Randy Jones incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

595. This cause of action is brought on behalf of the Louisiana-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

596. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to Louisiana Class Representatives and members of the Louisiana Class and was in the business of selling such products.

597. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

598. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

599. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

600. Defendant had reason to know Plaintiffs and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiffs and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

601. Plaintiffs and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

602. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

603. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

604. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiffs and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

605. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 23
Unjust Enrichment
(Louisiana Law)
(Against Pfizer)

606. Louisiana Class Representatives, Tammy Smith and Randy Jones incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

607. This cause of action is brought on behalf of the Louisiana-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

608. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

609. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

610. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and was knowingly enriched by its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

611. Defendant's enrichment – the monies obtained from Plaintiffs for the Ranitidine-Containing Products – was the result of Plaintiffs' impoverishment – the receipt by Plaintiffs of worthless Ranitidine-Containing Products that were unsafe and unfit for human consumption.

612. It is unjustifiable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

613. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

614. Plaintiffs and Class members do not have an adequate remedy at law, nor is there an express contract governing this dispute.

9. Causes of Action on Behalf of the Maryland-Pfizer Classes

COUNT 24
Violation of the Maryland Consumer Protection Act
(Md. Code Ann., Com. Law §13-101, *et seq.*)
(Against Pfizer)

615. Maryland Class Representatives Alberta Griffin, Charles Longfield, Ida Adams and Nicholas Hazlett incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

616. This cause of action is brought on behalf of the Maryland-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

617. Defendant, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Md. Code Ann., Com. Law §13-101(h).

618. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Md. Code Ann., Com. Law §13-101(c)(1).

619. The Ranitidine-Containing Products are "[m]erchandise" within the meaning of Md. Code Ann., Com. Law §13-101(f).

620. The Maryland Consumer Protection Act ("Maryland CPA") prohibits "[u]nfair, abusive, or deceptive trade practices." Md. Code Ann., Com. Law §13-301.

621. The Maryland CPA makes unlawful specific acts, including:

(a) "[f]alse, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity,

tendency, or effect of deceiving or misleading consumers" (Md. Code Ann., Com. Law §13-301(1));

(b) "[r]epresent[ing] that . . . [c]onsumer goods, consumer realty, or consumer services have a sponsorship, approval, accessory, characteristic, ingredient, use, benefit, or quantity which they do not have" (Md. Code Ann., Com. Law §13-301(2)(i));

(c) "[r]epresent[ing] that . . . [c]onsumer goods, consumer realty, or consumer services are of a particular standard, quality, grade, style, or model which they are not" (Md. Code Ann., Com. Law §13-301(2)(iv));

(d) "[f]ailure to state a material fact if the failure deceives or tends to deceive" (Md. Code Ann., Com. Law §13-301(3));

(e) "[a]dvertis[ing] or offer[ing] of consumer goods, consumer realty, or consumer services . . . [w]ithout intent to sell, lease, or rent them as advertised or offered" (Md. Code Ann., Com. Law §13-301(5)(i)); and

(f) "[d]eception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same in connection with . . . [t]he promotion or sale of any consumer goods" (Md. Code Ann., Com. Law §13-301(9)(i)).

622. In the course of its business, Defendant, through its agents, employees, and/or subsidiaries, violated the Maryland CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

623. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Maryland CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and thus resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

624. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Maryland CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

625. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive business practices prohibited by the Maryland CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised;

(d) failing to disclose that the Ranitidine-Containing Products are defective and inherently dangerous in the course of the sale of the Ranitidine-Containing Products; and

(e) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

626. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

627. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

628. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

629. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

630. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

631. Plaintiffs and the Class members relied on Defendant's misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendant's misrepresentations, omissions, and concealments were made.

632. Plaintiffs and the Class members were aggrieved by Defendant's violations of the Maryland CPA because they suffered ascertainable loss and actual damages as a direct and

proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

633. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

634. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

635. As a result of Defendant's violations of the Maryland CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Maryland CPA.

COUNT 25
Breach of Implied Warranty
(Md. Code Ann. §2-314)
(Against Pfizer)

636. Maryland Class Representatives Alberta Griffin, Charles Longfield, Ida Adams and Nicholas Hazlett incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

637. This cause of action is brought on behalf of the Maryland-Pfizer Class (for the purpose of this section, "Class") against Pfizer(for purposes of this Count only, "Defendant").

638. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to Maryland Class Representatives and members of the Maryland Class and was in the business of selling such products.

639. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

640. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

641. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

642. Defendant had reason to know Plaintiffs and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiffs and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

643. Plaintiffs and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

644. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

645. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

646. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiffs and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

647. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 26
Unjust Enrichment
(Maryland Law)
(Against Pfizer)

648. Maryland Class Representatives Alberta Griffin, Charles Longfield, Ida Adams and Nicholas Hazlett incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

649. This cause of action is brought on behalf of the Maryland-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

650. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

651. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products labels that exceeded the time period during which the products remained stable and thus resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

652. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and knowingly benefitted from its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products labels that exceeded the time period during which the products remained stable and thus resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

653. It would be unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

654. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts without paying for the value thereof, and therefore restitution or disgorgement of the amount of their unjust enrichment is required.

655. Plaintiffs and Class members do not have an adequate remedy at law.

10. Causes of Action on Behalf of the Michigan-Pfizer Classes

COUNT 27
Violation of the Michigan Consumer Protection Act
(Mich. Comp. Laws Ann. §445.901, *et seq.*)
(Against Pfizer)

656. Michigan Class Representatives Jerry Hunt, Kenneth Hix, and Lakisha Wilson incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

657. This cause of action is brought on behalf of the Michigan-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

658. Defendant, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Mich. Comp. Laws Ann. §445.902(1)(d).

659. Defendant was and is engaged in "[t]rade" or "commerce" within the meaning of Mich. Comp. Laws Ann. §445.902(1)(g).

660. The Michigan Consumer Protection Act ("Michigan CPA") prohibits "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce." Mich. Comp. Laws Ann. §445.903(1).

661. The Michigan CPA makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Mich. Comp. Laws Ann. §445.903(1)(c));

(b) "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" (Mich. Comp. Laws Ann. §445.903(1)(e)); and

(c) "[a]dvertising or representing goods or services with intent not to dispose of those goods or services as advertised or represented" (Mich. Comp. Laws Ann. §445.903(1)(g)).

662. In the course of its business, Defendant, through its agents, employees, and/or subsidiaries, violated the Michigan CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

663. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Michigan CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

664. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Michigan CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

665. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above,

Defendant engaged in one or more unfair or deceptive business practices prohibited by the Michigan CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

666. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

667. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

668. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

669. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii)

the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

670. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

671. Plaintiffs and the Class members were aggrieved by Defendant's violations of the Michigan CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

672. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

673. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

674. As a result of Defendant's violations of the Michigan CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Michigan CPA.

COUNT 28
Unjust Enrichment
(Michigan Law)
(Against Pfizer)

675. Michigan Class Representatives Jerry Hunt, Kenneth Hix, and Lakisha Wilson incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

676. This cause of action is brought on behalf of the Michigan-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

677. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

678. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

679. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and knowingly benefitted from its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which

the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

680. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

681. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

682. There is no express contract governing this dispute.

683. Plaintiffs and Class members do not have an adequate remedy at law.

11. Causes of Action on Behalf of the Minnesota-Pfizer Classes

COUNT 29
Violation of the Minnesota Prevention of Consumer Fraud Act
(Minn. Stat. Ann. §325F.68, *et seq.*)
(Against Pfizer)

684. Minnesota Class Representatives Donald Northrup, Roy Armstrong, and John Scholl incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

685. This cause of action is brought on behalf of the Minnesota-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

686. Defendant, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Minn. Stat. Ann. §325F.68(3).

687. The Ranitidine-Containing Products are "[m]erchandise" within the meaning of Minn. Stat. Ann. §325F.68(2).

688. The Minnesota Prevention of Consumer Fraud Act ("Minnesota CFA") prohibits "act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged." Minn. Stat. Ann. §325F.69(1). Prohibited practices include: (i) deceptive practices concerning the quality of goods or services pursuant to Minn. Stat. Ann. §325D.44; (ii) fraud in connection with the sale of any merchandise pursuant to Minn. Stat. Ann. §325F.69; and (iii) misrepresentation of product ingredients or quality pursuant to Minn. Stat. Ann. §325D.13.

689. In the course of its business, Defendant, through its agents, employees, and/or subsidiaries, violated the Minnesota CFA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

690. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Minnesota CFA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

691. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Minnesota CFA by knowingly and intentionally misrepresenting, omitting, concealing, and

failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

692. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive business practices prohibited by the Minnesota CFA.

693. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

694. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

695. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

696. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii)

the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

697. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

698. Plaintiffs and the Class members relied on Defendant's misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendant's misrepresentations, omissions, and concealments were made.

699. Plaintiffs and the Class members were aggrieved by Defendant's violations of the Minnesota CFA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

700. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

701. Defendant's violations present a continuing risk to Plaintiff and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

702. As a result of Defendant's violations of the Minnesota CFA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Minnesota CFA.

COUNT 30
Breach of Implied Warranty
(Minn. Stat. Ann. §336.2-314)
(Against Pfizer)

703. Minnesota Class Representatives Donald Northrup, Roy Armstrong, and John Scholl incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

704. This cause of action is brought on behalf of the Minnesota-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

705. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to Minnesota Class Representatives and members of the Minnesota Class and was in the business of selling such products.

706. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

707. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

708. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

709. Defendant had reason to know Plaintiffs and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiffs and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

710. Plaintiffs and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

711. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

712. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

713. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiffs and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

714. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 31
Unjust Enrichment
(Minnesota Law)
(Against Pfizer)

715. Minnesota Class Representatives Donald Northrup, Roy Armstrong, and John Scholl incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

716. This cause of action is brought on behalf of the Minnesota-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

717. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

718. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

719. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and knowingly benefitted from its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

720. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

721. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts without paying for said benefits, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

722. Plaintiffs and Class members do not have an adequate remedy at law.

12. Causes of Action Brought on Behalf of the Mississippi-Pfizer Classes

COUNT 32
Breach of Implied Warranty
(Miss. Code Ann. §75-2-314)
(Against Pfizer)

723. Mississippi Class Representatives Beverly Crosby and John Rachal incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

724. This cause of action is brought on behalf of the Mississippi-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

725. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to the Mississippi Class Representative and members of the Mississippi Class and was in the business of selling such products.

726. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

727. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

728. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

729. Defendant had reason to know Plaintiffs and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiffs and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

730. Plaintiffs and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

731. Plaintiffs and each member of the Class has had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

732. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

733. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiffs and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

734. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 33
Unjust Enrichment
(Mississippi Law)
(Against Pfizer)

735. Mississippi Class Representatives Beverly Crosby and John Rachal incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

736. This cause of action is brought on behalf of the Mississippi-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

737. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

738. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members suffered a detriment because they purchased worthless medications and did not receive the expected benefit therefrom.

739. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and was knowingly enriched by its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which

the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

740. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

741. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

742. There is no express contract governing this dispute.

743. Plaintiffs and Class members do not have an adequate remedy at law.

13. Causes of Action on Behalf of the Missouri-Pfizer Classes

COUNT 34
Violation of the Missouri Merchandising Practices Act
(Mo. Ann. Stat. §407.010, *et seq.*)
(Against Pfizer)

744. Missouri Class Representatives Tammy Smith and Ronda Lockett incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

745. This cause of action is brought on behalf of the Missouri-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

746. Defendant, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Mo. Ann. Stat. §407.010(5).

747. Defendant was and is engaged in "[t]rade or commerce" within the meaning of Mo. Ann. Stat. §407.010(7).

748. The Missouri Merchandising Practices Act ("Missouri MPA") prohibits "act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce." Mo. Ann. Stat. §407.020(1).

749. In the course of its business, Defendant, through its agents, employees, and/or subsidiaries, violated the Missouri MPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

750. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Missouri MPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

751. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Missouri MPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

752. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive business practices prohibited by the Missouri MPA.

753. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

754. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

755. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

756. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

757. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered

material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

758. Plaintiffs and the Class members were aggrieved by Defendant's violations of the Missouri MPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

759. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

760. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

761. As a result of Defendant's violations of the Missouri MPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Missouri MPA.

COUNT 35
Breach of Implied Warranty
(Mo. Rev. Stat. §400.2-314)
(Against Pfizer)

762. Missouri Class Representatives Tammy Smith and Ronda Lockett incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

763. This cause of action is brought on behalf of the Missouri-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

764. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to the Missouri Class Representative and members of the Missouri Class and was in the business of selling such products.

765. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

766. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

767. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

768. Defendant had reason to know Plaintiff and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiffs and each

member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

769. Plaintiffs and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

770. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

771. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

772. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiffs and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

773. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 36
Unjust Enrichment
(Missouri Law)
(Against Pfizer)

774. Missouri Class Representatives Tammy Smith and Ronda Lockett incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

775. This cause of action is brought on behalf of the Missouri-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

776. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

777. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

778. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and knowingly benefitted from its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which

the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

779. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

780. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts without paying for said benefits, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

781. There is no express contract governing this dispute.

782. Plaintiffs and Class members do not have an adequate remedy at law.

14. Causes of Action on Behalf of the Nebraska-Pfizer Classes

COUNT 37
Violation of the Nebraska Consumer Protection Act
(Neb. Rev. Stat. Ann. §59-1601, *et seq.*)
(Against Pfizer)

783. Nebraska Class Representative Gaylord Stauffer incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

784. This cause of action is brought on behalf of the Nebraska-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

785. Defendant, Plaintiff, and the Class members are "[p]erson[s]" within the meaning of Neb. Rev. Stat. Ann. §59-1601(1).

786. The Ranitidine-Containing Products are "[a]ssets" within the meaning of Neb. Rev. Stat. Ann. §59-1601(3).

787. Defendant was and is engaged in "[t]rade" or "commerce" within the meaning of Neb. Rev. Stat. Ann. §59-1601(2).

788. The Nebraska Consumer Protection Act ("Nebraska CPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Neb. Rev. Stat. Ann. §59-1602.

789. In the course of its business, Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Nebraska CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

790. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Nebraska CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

791. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Nebraska CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably

dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

792. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Nebraska CPA.

793. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

794. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

795. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

796. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

797. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiff and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

798. Plaintiff and the Class members were aggrieved by Defendant's violations of the Nebraska CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

799. Specifically, Plaintiff and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiff and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

800. Defendant's violations present a continuing risk to Plaintiff and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

801. As a result of Defendant's violations of the Nebraska CPA, as alleged herein, Plaintiff and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Nebraska CPA.

COUNT 38
Breach of Implied Warranty
(Neb. U.C.C. §2-314)
(Against Pfizer)

802. Nebraska Class Representative Gaylord Stauffer incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

803. This cause of action is brought on behalf of the Nebraska-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

804. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to Nebraska Class Representatives and members of the Nebraska Class and was in the business of selling such products.

805. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

806. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

807. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

808. Defendant had reason to know Plaintiff and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products, and knew that Plaintiffs and each

member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

809. Plaintiff and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

810. Plaintiff and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiff and each member of the Class, on the other hand.

811. Further, Plaintiff and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

812. Plaintiff and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiff and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

813. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiff and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 39
Unjust Enrichment
(Nebraska Law)
(Against Pfizer)

814. Nebraska Class Representative Gaylord Stauffer incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

815. This cause of action is brought on behalf of the Nebraska-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

816. Plaintiff and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

817. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiff and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiff and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

818. Defendant readily accepted and retained these benefits from Plaintiff and Class members and knowingly benefitted from its unjust conduct – at Plaintiff's and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which

the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

819. It is unjust and unfair for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiff and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

820. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiff and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

821. There is no express contract governing this dispute.

822. Plaintiff and Class members do not have an adequate remedy at law.

15. Causes of Action on Behalf of the Nevada-Pfizer Classes

COUNT 40
Violation of the Nevada Deceptive Trade Practices Act
(Nev. Rev. Stat. Ann. §598.0903, *et seq.*)
(Against Pfizer)

823. Nevada Class Representative Jonathan Ferguson incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

824. This cause of action is brought on behalf of the Nevada-Pfizer Class (for the purpose of this section, "Class") against Pfizer with respect to OTC Zantac purchases (for purposes of this Count only, "Defendant").

825. The Nevada Deceptive Trade Practices Act ("Nevada DTPA"), prohibits the use of "'deceptive trade practices' . . . in the course of . . . business or occupation." Nev. Rev. Stat. Ann. §598.0915.

826. The Nevada DTPA makes unlawful specific acts, including:

(a) "[k]nowingly mak[ing] a false representation as to the characteristics, ingredients, uses, benefits, alterations or quantities of goods or services for sale or lease or a false representation as to the sponsorship, approval, status, affiliation or connection of a person therewith" (Nev. Rev. Stat. Ann. §598.0915(5));

(b) "[r]epresent[ing] that goods or services for sale or lease are of a particular standard, quality or grade, or that such goods are of a particular style or model, if he or she knows or should know that they are of another standard, quality, grade, style or model" (Nev. Rev. Stat. Ann. §598.0915(7));

(c) "[a]dvertis[ing] goods or services with intent not to sell or lease them as advertised" (Nev. Rev. Stat. Ann. §598.0915(9));

(d) "[k]nowingly mak[ing] any other false representation in a transaction" (Nev. Rev. Stat. Ann. §598.0915(15)); and

(e) "[f]ail[ing] to disclose a material fact in connection with the sale or lease of goods or services" (Nev. Rev. Stat. Ann. §598.0923(2)).

827. In the course of its business, Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Nevada DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

828. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Nevada DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and thus resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

829. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Nevada DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

830. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Nevada DTPA, including:

(a) representing that Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised;

(d) failing to disclose the NDMA danger in connection with the sale of the Ranitidine-Containing Products; and

(e) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

831. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

832. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

833. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

834. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

835. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiff and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

836. Plaintiff and the Class members were aggrieved by Defendant's violations of the Nevada DTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

837. Specifically, Plaintiff and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices

alleged herein, Plaintiff and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

838. Defendant's violations present a continuing risk to Plaintiff and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

839. As a result of Defendant's violations of the Nevada DTPA, as alleged herein, Plaintiff and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Nevada DTPA.

COUNT 41
Unjust Enrichment
(Nevada Law)
(Against Pfizer)

840. Nevada Class Representative Jonathan Ferguson incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

841. This cause of action is brought on behalf of the Nevada-Pfizer Class (for the purpose of this section, "Class") against Brand Manufacturer Defendant Pfizer with respect to Zantac OTC purchases (for purposes of this Count only, "Defendant").

842. Plaintiff and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

843. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiff and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe

and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products labels that exceeded the time period during which the products remained stable and thus resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiff and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

844. Defendant readily accepted and retained these benefits from Plaintiff and Class members and knowingly benefitted from its unjust conduct – at Plaintiff's and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products labels that exceeded the time period during which the products remained stable and thus resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

845. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiff and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

846. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiff and Class members through its unjust and unlawful acts, and therefore restitution or disgorgement of the amount of their unjust enrichment is required.

847. There is no express contract governing this dispute.

848. Plaintiff and Class members do not have an adequate remedy at law.

16. Causes of Action on Behalf of the New York-Pfizer Classes

COUNT 42
Violation of New York Deceptive Acts and Practices Act
(N.Y. Gen. Bus. Law §349)
(Against Pfizer)

849. New York Class Representatives Dan Zhovtis and Mary McCullen incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

850. This cause of action is brought on behalf of the New York-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

851. Plaintiffs and the Class members are "person[s]" within the meaning of N.Y. Gen. Bus. Law §349(h). Defendant is a "person, firm, corporation or association" within the meaning of N.Y. Gen. Bus. Law §349(b).

852. The New York Deceptive Acts and Practices Act ("New York DAPA") prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law §349(a).

853. In the course of its business, Defendant, directly or through its agents, employees, and/or subsidiaries, violated the New York DAPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

854. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the New York DAPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by

printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

855. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the New York DAPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

856. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the New York DAPA.

857. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

858. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

859. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

860. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

861. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

862. Plaintiffs and the Class members were aggrieved by Defendant's violations of the New York DAPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

863. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

864. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

865. As a result of Defendant's violations of the New York DAPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the New York DAPA.

COUNT 43
Violation of the New York False Advertising Act
(N.Y. Gen. Bus. Law §350)
(Against Pfizer)

866. New York Class Representatives Dan Zhovtis and Mary McCullen incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

867. This cause of action is brought on behalf of the New York-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

868. Defendant was and is engaged in "conduct of business, trade or commerce" within the meaning of N.Y. Gen. Bus. Law §350.

869. The New York False Advertising Act ("New York FAA") prohibits "[f]alse advertising in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law §350. False advertising includes "advertising, including labeling, of a commodity . . . if such advertising is misleading in a material respect," taking into account "the extent to which the advertising fails to reveal facts material in the light of . . . representations [made] with respect to the commodity." N.Y. Gen. Bus. Law §350-a(1).

870. Defendant caused to be made or disseminated through New York and the United States, through advertising, marketing, and other publications, statements that were untrue or misleading, and which were known, or which by exercise of reasonable care should have been known to Defendant, to be untrue and misleading to consumers, including Plaintiffs and the Class members.

871. In the course of its business, Defendant, directly or through its agents, employees, and/or subsidiaries, violated the New York FAA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

872. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the New York FAA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

873. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the New York FAA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

874. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the New York FAA.

875. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

876. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

877. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

878. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

879. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered

material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

880. Plaintiffs and the Class members were aggrieved by Defendant's violations of the New York FAA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

881. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

882. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

883. Defendant was provided notice of the issues raised in this Count and this Complaint by the FDA investigations, the numerous complaints filed against it, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter to Defendant. Because Defendant failed to adequately remedy its unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Class members are entitled.

884. As a result of Defendant's violations of the New York FAA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the New York FAA.

COUNT 44
Breach of Implied Warranty
(N.Y. U.C.C. Law §2-314)
(Against Pfizer)

885. New York Class Representatives Dan Zhovtis and Mary McCullen incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

886. This cause of action is brought on behalf of the New York-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

887. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to New York Class Representative and members of the New York Class and was in the business of selling such products.

888. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

889. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

890. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

891. Defendant had reason to know Plaintiffs and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiffs and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

892. Plaintiffs and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

893. Plaintiffs and each member of the Class has had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

894. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

895. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiffs and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of

merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

896. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 45
Unjust Enrichment
(New York Law)
(Against Pfizer)

897. New York Class Representatives Dan Zhovtis and Mary McCullen incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

898. This cause of action is brought on behalf of the New York-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

899. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

900. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly,

Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

901. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and knowingly benefitted from its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

902. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

903. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

904. Plaintiffs and Class members do not have an adequate remedy at law, nor is there an express contract governing this dispute.

17. Causes of Action on Behalf of the North Carolina-Pfizer Classes

COUNT 46
Violation of the North Carolina Unfair and Deceptive Trade Practices Act
(N.C. Gen. Stat. Ann. §75-1.1, *et seq.*)
(Against Pfizer)

905. North Carolina Class Representative Dennis Robbins incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

906. This cause of action is brought on behalf of the North Carolina-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

907. Defendant was and is engaged in "commerce" within the meaning of N.C. Gen. Stat. Ann. §75-1.1(b).

908. The North Carolina Unfair and Deceptive Trade Practices Act ("North Carolina UDTPA") prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce," N.C. Gen. Stat. Ann. §75-1.1(a), and provides a private right of action for any person injured "by reason of any act or thing done by any other person, firm or corporation in violation of" the law. N.C. Gen. Stat. Ann. §75-16.

909. In the course of its business, Defendant, directly or through its agents, employees, and/or subsidiaries, violated the North Carolina UDTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

910. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the North Carolina UDTPA by knowingly and intentionally misrepresenting, omitting, concealing,

and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

911. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the North Carolina UDTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

912. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the North Carolina UDTPA.

913. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

914. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

915. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of

Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

916. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

917. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiff and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

918. Plaintiff and the Class members were aggrieved by Defendant's violations of the North Carolina UDTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

919. Specifically, Plaintiff and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiff and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

920. Defendant's violations present a continuing risk to Plaintiff and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

921. As a result of Defendant's violations of the North Carolina UDTPA, as alleged herein, Plaintiff and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the North Carolina UDTPA.

COUNT 47
Breach of Implied Warranty
(N.C. Gen. Stat. Ann. §25-2-314)
(Against Pfizer)

922. North Carolina Class Representative Dennis Robbins incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

923. This cause of action is brought on behalf of the North Carolina-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

924. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to North Carolina Class Representatives and members of the North Carolina Class and was in the business of selling such products.

925. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

926. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

927. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

928. Defendant had reason to know Plaintiff and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiff and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

929. Plaintiff and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

930. Plaintiff and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiff and each member of the Class, on the other hand.

931. Further, Plaintiff and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

932. Plaintiff and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiff and the members of

the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

933. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiff and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 48
Unjust Enrichment
(North Carolina Law)
(Against Pfizer)

934. North Carolina Class Representatives Dennis Robbins incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

935. This cause of action is brought on behalf of the North Carolina-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

936. Plaintiff and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

937. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiff and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly,

Plaintiff and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

938. Defendant readily accepted and retained these benefits from Plaintiff and Class members and knowingly benefitted from its unjust conduct – at Plaintiff's and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

939. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiff and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

940. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiff and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

941. Plaintiff and Class members do not have an adequate remedy at law, nor is there an express contract governing this dispute.

18. Causes of Action on Behalf of the North Dakota-Pfizer Classes

COUNT 49
Violation of the North Dakota Consumer Fraud Act
(N.D. Cent. Code Ann. §51-15-02)
(Against Pfizer)

942. North Dakota Class Representative John Scholl incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

943. This cause of action is brought on behalf of the North Dakota-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

944. Defendant, Plaintiff, and the Class members are "[p]erson[s]" within the meaning of N.D. Cent. Code Ann. §51-15-01(4).

945. The Ranitidine-Containing Products are "[m]erchandise" within the meaning of N.D. Cent. Code Ann. §51-15-01(3).

946. The North Dakota Consumer Fraud Act ("North Dakota CFA") prohibits "[t]he act, use, or employment by any person of any deceptive act or practice, fraud, false pretense, false promise, or misrepresentation, with the intent that others rely thereon in connection with the sale or advertisement of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby." N.D. Cent. Code Ann. §51-15-02.

947. In the course of its business, Defendant, directly or through its agents, employees, and/or subsidiaries, violated the North Dakota CFA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

948. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the North Dakota CFA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

949. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the North Dakota CFA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

950. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the North Dakota CFA.

951. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

952. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

953. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

954. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

955. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiff and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

956. Plaintiff and the Class members were aggrieved by Defendant's violations of the North Dakota CFA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

957. Specifically, Plaintiff and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices

alleged herein, Plaintiff and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

958. Defendant's violations present a continuing risk to Plaintiff and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

959. As a result of Defendant's violations of the North Dakota CFA, as alleged herein, Plaintiff and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the North Dakota CFA.

COUNT 50
Unjust Enrichment
(North Dakota Law)
(Against Pfizer)

960. North Dakota Class Representative John Scholl incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

961. This cause of action is brought on behalf of the North Dakota-Pfizer Class (for the purpose of this section, "Class") against Brand Manufacturer Defendant Pfizer (for purposes of this Count only, "Defendant").

962. Plaintiff and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products, or were otherwise in privity with Defendant through said transaction.

963. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiff and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe

and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiff and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

964. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and was knowingly enriched by its unjust conduct – at Plaintiff's and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

965. Defendant's enrichment – the monies obtained from Plaintiff's and Class members' purchases of Ranitidine-Containing Products – was the result of Plaintiff's and Class members' impoverishment – *i.e.*, Plaintiff's and Class members' receipt of worthless Ranitidine-Containing Products that were unsafe and unfit for human consumption.

966. It is unjustifiable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiff and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

967. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiff and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

968. Plaintiff and Class members do not have an adequate remedy at law, nor is there an express contract governing this dispute.

19. Causes of Action on Behalf of the Ohio-Pfizer Classes

COUNT 51
Breach of Implied Warranty
(Ohio Rev. Code Ann. §1302.27)
(Against Pfizer)

969. Ohio Class Representatives Michael Galloway and Chris Troyan incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

970. This cause of action is brought on behalf of the Ohio-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

971. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to the Ohio Class Representatives and members of the Ohio Class and was in the business of selling such products.

972. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

973. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

974. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

975. Defendant had reason to know Plaintiffs and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiffs and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

976. Plaintiffs and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

977. Plaintiffs and each member of the Class has had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

978. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

979. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiffs and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

980. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 52
Unjust Enrichment
(Ohio Law)
(Against Pfizer)

981. Ohio Class Representatives Michael Galloway and Chris Troyan incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

982. This cause of action is brought on behalf of the Ohio Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

983. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

984. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

985. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and knowingly benefitted from its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

986. It is unjust for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

987. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts without paying for said benefits, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

988. Plaintiffs and Class members do not have an adequate remedy at law, nor is there an express contract governing this dispute.

20. Causes of Action on Behalf of Oregon-Pfizer Classes

COUNT 53
Violation of the Oregon Unlawful Trade Practices Act
(Or. Rev. Stat. Ann. §646.605, *et seq.*)
(Against Pfizer)

989. Oregon Class Representative Jonathan Ferguson incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

990. This cause of action is brought on behalf of the Oregon-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

991. Defendant, Plaintiff, and the Class members are "[p]erson[s]" within the meaning of Or. Rev. Stat. Ann. §646.605(4).

992. The Ranitidine-Containing Products are "goods" within the meaning of Or. Rev. Stat. Ann. §646.605(6).

993. Defendant was and is engaged in "[t]rade" or "commerce" within the meaning of Or. Rev. Stat. Ann. §646.605(8).

994. The Oregon Unlawful Trade Practices Act ("Oregon UTPA") prohibits "unlawful practice . . . in the course of the person's business." Or. Rev. Stat. Ann. §646.608(1).

995. The Oregon UTPA makes unlawful specific acts, including:

(a) "[r]epresent[ing] that real estate, goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities or qualities that the real estate, goods or services do not have" (Or. Rev. Stat. Ann. §646.608(1)(e));

(b) "[r]epresent[ing] that real estate, goods or services are of a particular standard, quality, or grade, or that real estate or goods are of a particular style or model, if the real estate, goods or services are of another" (Or. Rev. Stat. Ann. §646.608(1)(g));

(c) "[a]dvertis[ing] real estate, goods or services with intent not to provide the real estate, goods or services as advertised" (Or. Rev. Stat. Ann. §646.608(1)(i)); and

(d) "[e]ngag[ing] in any other unfair or deceptive conduct in trade or commerce" (Or. Rev. Stat. Ann. §646.608(1)(u)).

996. In the course of its business, Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Oregon UTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably

dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

997. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Oregon UTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

998. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Oregon UTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

999. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Oregon UTPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not;

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

1000. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

1001. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

1002. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

1003. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

1004. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiff and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1005. Plaintiff and the Class members were aggrieved by Defendant's violations of the Oregon UTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

1006. Specifically, Plaintiff and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiff and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1007. Defendant's violations present a continuing risk to Plaintiff and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

1008. As a result of Defendant's violations of the Oregon UTPA, as alleged herein, Plaintiff and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Oregon UTPA.

COUNT 54
Breach of Implied Warranty
(Or. Rev. Stat. §72.3140)
(Against Pfizer)

1009. Oregon Class Representative Jonathan Ferguson incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1010. This cause of action is brought on behalf of the Oregon-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1011. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to Oregon Class Representatives and members of the Oregon Class and was in the business of selling such products.

1012. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1013. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1014. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

1015. Defendant had reason to know Plaintiff and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products, and knew that Plaintiff and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1016. Plaintiff and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1017. Plaintiff and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiff and each member of the Class, on the other hand.

1018. Further, Plaintiff and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

1019. Plaintiff and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiff and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1020. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiff and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 55
Unjust Enrichment
(Oregon Law)
(Against Pfizer)

1021. Oregon Class Representative Jonathan Ferguson incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1022. This cause of action is brought on behalf of the Oregon-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1023. Plaintiff and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products, or were otherwise in privity with Defendant through said transaction.

1024. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiff and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiff and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

1025. Defendant readily accepted and retained these benefits from Plaintiff and Class members and knowingly benefitted from its unjust conduct – at Plaintiff's and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

1026. It is unjust for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiff and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

1027. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiff and Class members through its unjust and unlawful acts without paying for said benefits, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

1028. There is no express contract governing this dispute.

1029. Plaintiff and Class members do not have an adequate remedy at law.

21. Causes of Action Brought on Behalf of Puerto Rico-Pfizer Classes

COUNT 56
Breach of Implied Warranty
(P.R. Laws Ann. tit. 31, §3841)
(Against Pfizer)

1030. Puerto Rico Class Representatives Gloria Colon and Sonia Diaz incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1031. This cause of action is brought on behalf of the Puerto Rico-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1032. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to Puerto Rico Class Representatives and members of the Puerto Rico Class and was in the business of selling such products.

1033. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1034. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1035. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

1036. Defendant had reason to know Plaintiff and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products, and knew that Plaintiff and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1037. Plaintiff and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1038. Plaintiff and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiff and each member of the Class, on the other hand.

1039. Further, Plaintiff and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

1040. Plaintiff and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiff and the members of

the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1041. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiff and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 57
Unjust Enrichment
(Puerto Rico Law)
(Against Pfizer)

1042. Puerto Rico Class Representatives Gloria Colon and Sonia Diaz incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1043. This cause of action is brought on behalf of the Puerto Rico-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1044. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

1045. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly,

Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

1046. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and was knowingly enriched by its unjust conduct – at Plaintiff's and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

1047. Defendant's enrichment – the monies obtained from Plaintiffs' and Class members' purchases of Ranitidine-Containing Products – was the result of Plaintiffs' and Class members' impoverishment – *i.e.*, Plaintiffs' and Class members' receipt of worthless Ranitidine-Containing Products that were unsafe and unfit for human consumption.

1048. It is unjustifiable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

1049. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

1050. Plaintiffs and Class members do not have an adequate remedy at law.

22. Causes of Action on Behalf of Tennessee-Pfizer Classes

COUNT 58
Violation of the Tennessee Consumer Protection Act of 1977
(Tenn. Code Ann. §47-18-101, *et seq.*)
(Against Pfizer)

1051. Tennessee Class Representative Dale Hunter incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1052. This cause of action is brought on behalf of the Tennessee-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1053. Defendant, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Tenn. Code Ann. §47-18-103(14).

1054. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Tenn. Code Ann. §47-18-103(3).

1055. The Ranitidine-Containing Products are "[g]oods" within the meaning of Tenn. Code Ann. §47-18-103(8).

1056. Defendant was and is engaged in "[t]rade" or "commerce" or "consumer transaction[s]" within the meaning of Tenn. Code Ann. §47-18-103(20).

1057. The Tennessee Consumer Protection Act of 1977 ("Tennessee CPA") prohibits "[u]nfair or deceptive acts or practices affecting the conduct of any trade or commerce." Tenn. Code Ann. §47-18-104(a).

1058. The Tennessee CPA makes unlawful specific acts, including:

(a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Tenn. Code Ann. §47-18-104(b)(5));

(b) "[r]epresenting that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another" (Tenn. Code Ann. §47-18-104(b)(7)); and

(c) "[a]dvertising goods or services with intent not to sell them as advertised" (Tenn. Code Ann. §47-18-104(b)(9)).

1059. In the course of its business, Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Tennessee CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

1060. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Tennessee CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

1061. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Tennessee CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

1062. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Tennessee CPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not; and

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised.

1063. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1064. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1065. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1066. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

1067. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered

material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1068. Plaintiffs and the Class members were aggrieved by Defendant's violations of the Tennessee CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

1069. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1070. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

1071. As a result of Defendant's violations of the Tennessee CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Tennessee CPA.

COUNT 59
Breach of Implied Warranty
(Tenn. Code Ann. §47-2-314)
(Against Pfizer)

1072. Tennessee Class Representative Dale Hunter incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1073. This cause of action is brought on behalf of the Tennessee-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1074. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to Tennessee Class Representatives and members of the Tennessee Class and was in the business of selling such products.

1075. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1076. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1077. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

1078. Defendant had reason to know Plaintiffs and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiffs and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1079. Plaintiffs and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1080. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1081. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

1082. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiffs and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1083. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 60
Unjust Enrichment
(Tennessee Law)
(Against Pfizer)

1084. Tennessee Class Representative Dale Hunter incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1085. This cause of action is brought on behalf of the Tennessee-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1086. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

1087. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

1088. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and knowingly benefitted from its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

1089. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the

Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

1090. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts without paying for said benefits, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

1091. There is no existing, enforceable contract governing this dispute.

1092. Plaintiffs and Class members do not have an adequate remedy at law.

23. Causes of Action on Behalf of the Texas-Pfizer Classes

COUNT 61
Violation of the Texas Deceptive Trade Practices-Consumer Protection Act
(Tex. Bus. & Com. Code Ann. §17.41, *et seq.*)
(Against Pfizer)

1093. Texas Class Representatives Marianella Villanueva, Ronda Lockett, Sylvia Yoshida, and Tammy Smith incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1094. This cause of action is brought on behalf of the Texas-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1095. Defendant, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Tex. Bus. & Com. Code Ann. §17.45(3).

1096. Plaintiffs and the Class members are "[c]onsumer[s]" within the meaning of Tex. Bus. & Com. Code Ann. §17.45(4).

1097. The Ranitidine-Containing Products are "[g]oods" within the meaning of Tex. Bus. & Com. Code Ann. §17.45(1).

1098. Defendant was and is engaged in "[t]rade" or "commerce" within the meaning of Tex. Bus. & Com. Code Ann. §17.45(6).

1099. The Texas Deceptive Trade Practices-Consumer Protection Act ("Texas DTPA") prohibits "[f]alse, misleading, or deceptive acts or practices in the conduct of any trade or commerce," Tex. Bus. & Com. Code Ann. §17.46(a), and an "[u]nconscionable action or course of action," which means "an act or practice which, to a consumer's detriment, takes advantage of the lack of knowledge, ability, experience, or capacity of the consumer to a grossly unfair degree." Tex. Bus. & Com. Code Ann. §§17.45(5) and 17.50(a)(3).

1100. The Texas DTPA makes unlawful specific acts, including:

(a) "representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" (Tex. Bus. & Com. Code Ann. §17.46(5));

(b) "representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" (Tex. Bus. & Com. Code Ann. §17.46(7)); and

(c) "advertising goods or services with intent not to sell them as advertised" (Tex. Bus. & Com. Code Ann. §17.46(9)).

1101. In the course of its business, Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Texas DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

1102. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Texas DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing

expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

1103. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Texas DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

1104. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Texas DTPA, including:

(a) representing that the Ranitidine-Containing Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the Ranitidine-Containing Products are of a particular standard, quality, and grade when they are not; and

(c) advertising the Ranitidine-Containing Products with the intent not to sell them as advertised.

1105. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

1106. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1107. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1108. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

1109. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1110. Plaintiffs and the Class members relied on Defendant's misrepresentations, omissions, and concealments with respect to Ranitidine-Containing Products by purchasing and continuing to purchase Ranitidine-Containing Products after Defendant's misrepresentations, omissions, and concealments were made.

1111. Plaintiffs and the Class members were aggrieved by Defendant's violations of the Texas DTPA because they suffered ascertainable loss and actual damages as a direct and proximate

result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

1112. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1113. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

1114. Defendant was provided notice of the issues raised in this Count and this Complaint by the FDA investigations, the numerous complaints filed against it, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of Ranitidine-Containing Products' defects became public. In addition, on May 21, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to Tex. Bus. & Com. Code Ann. §17.505(a) to Defendant. Because Defendant failed to adequately remedy its unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiff and the Class members are entitled.

1115. As a result of Defendant's violations of the Texas DTPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Texas DTPA.

COUNT 62
Breach of Implied Warranty
(Tex. Bus. & Com. Code Ann. §2-314)
(Against Pfizer)

1116. Texas Class Representatives Marianella Villanueva, Ronda Lockett, Sylvia Yoshida, and Tammy Smith incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1117. This cause of action is brought on behalf of the Texas-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1118. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to Texas Class Representatives and members of the Texas Class and was in the business of selling such products.

1119. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1120. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1121. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

1122. Defendant had reason to know Plaintiffs and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiffs and each

member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1123. Plaintiffs and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1124. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1125. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

1126. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiffs and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1127. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 63
Unjust Enrichment
(Texas Law)
(Against Pfizer)

1128. Texas Class Representatives Marianella Villanueva, Ronda Lockett, Sylvia Yoshida, and Tammy Smith incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1129. This cause of action is brought on behalf of the Texas-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1130. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

1131. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

1132. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and knowingly benefitted from its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which

the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

1133. It is unjust and unconscionable for the Defendant to retain these wrongly secured benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

1134. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts without paying for said benefits, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

1135. Plaintiffs and Class members do not have an adequate remedy at law, nor is there an express contract governing this dispute.

24. Causes of Action on Behalf of the Washington-Pfizer Classes

COUNT 64
Violation of the Washington Consumer Protection Act
(Wash. Rev. Code Ann. §19.86.010, *et seq.*)
(Against Pfizer)

1136. Washington Class Representatives Earlene Green, Steve Fischer, and Jonathan Ferguson incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1137. This cause of action is brought on behalf of the Washington-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1138. Defendant, Plaintiffs, and the Class members are "[p]erson[s]" within the meaning of Wash. Rev. Code Ann. §19.86.010(1).

1139. The Ranitidine-Containing Products are "[a]ssets" within the meaning of Wash. Rev. Code Ann. §19.86.010(3).

1140. Defendant was and is engaged in "[t]rade" or "commerce" within the meaning of Wash. Rev. Code Ann. §19.86.010(2).

1141. The Washington Consumer Protection Act ("Washington CPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Wash. Rev. Code Ann. §19.86.020.

1142. In the course of its business, Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Washington CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

1143. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Washington CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

1144. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Washington CPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably

dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

1145. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Washington CPA.

1146. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1147. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1148. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiffs and the Class members in a uniform manner.

1149. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

1150. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1151. Plaintiffs and the Class members were aggrieved by Defendant's violations of the Washington CPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

1152. Specifically, Plaintiffs and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiffs and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1153. Defendant's violations present a continuing risk to Plaintiffs and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

1154. On June 22, 2020, Plaintiffs in MDL 2924 sent a notice letter pursuant to Wash. Rev. Code Ann. §19.86.095 to the Attorney General of the State of Washington.

1155. As a result of Defendant's violations of the Washington CPA, as alleged herein, Plaintiffs and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Washington CPA.

COUNT 65
Breach of Implied Warrant
(Wash. Rev. Code §62A.2-314)
(Against Pfizer)

1156. Washington Class Representatives Earlene Green, Steve Fischer, and Jonathan Ferguson incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1157. This cause of action is brought on behalf of the Washington-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1158. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to Washington Class Representatives and members of the Washington Class and was in the business of selling such products.

1159. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1160. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1161. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

1162. Defendant had reason to know Plaintiffs and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products, and knew that Plaintiffs and each

member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1163. Plaintiffs and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1164. Plaintiffs and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiffs and each member of the Class, on the other hand.

1165. Further, Plaintiffs and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

1166. Plaintiffs and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiffs and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1167. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiffs and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 66
Unjust Enrichment
(Washington Law)
(Against Pfizer)

1168. Washington Class Representatives Earlene Green, Steve Fischer, and Jonathan Ferguson incorporate the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1169. This cause of action is brought on behalf of the Washington-Pfizer Class (for the purpose of this section, "Class") against Brand Manufacturer Defendant Pfizer (for purposes of this Count only, "Defendant").

1170. Plaintiffs and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products, or were otherwise in privity with Defendant through said transaction.

1171. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiffs and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiffs and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

1172. Defendant readily accepted and retained these benefits from Plaintiffs and Class members and knowingly benefitted from its unjust conduct – at Plaintiffs' and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and

that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

1173. It is unjust for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiffs and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

1174. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiffs and Class members through its unjust and unlawful acts without paying for said benefits, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

1175. There is no express contract governing this dispute.

1176. Plaintiffs and Class members do not have an adequate remedy at law.

25. Causes of Action on Behalf of the West Virginia-Pfizer Classes

COUNT 67
Breach of Implied Warranty
(W. Va. Code §46-2-314)
(Against Pfizer)

1177. West Virginia Class Representative Ida Adams incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1178. This cause of action is brought on behalf of the West Virginia-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1179. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to West Virginia Class Representatives and members of the West Virginia Class and was in the business of selling such products.

1180. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1181. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1182. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

1183. Defendant had reason to know Plaintiff and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiff and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1184. Plaintiff and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1185. Plaintiff and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiff and each member of the Class, on the other hand.

1186. Further, Plaintiff and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

1187. Plaintiff and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiff and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiff and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 68
Unjust Enrichment
(West Virginia Law)
(Against Pfizer)

1188. West Virginia Class Representative Ida Adams incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1189. This cause of action is brought on behalf of the West Virginia-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1190. Plaintiff and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products, or were otherwise in privity with Defendant through said transaction.

1191. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiff and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiff and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

1192. Defendant readily accepted and retained these benefits from Plaintiff and Class members and knowingly benefitted from its unjust conduct – at Plaintiff's and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

1193. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiff and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

1194. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiff and Class members through its unjust and unlawful acts without paying for said benefits, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

1195. There is no express contract governing this dispute.

1196. Plaintiff and Class members do not have an adequate remedy at law.

26. Causes of Action on Behalf of the Wisconsin-Pfizer Classes

COUNT 69
Violation of the Wisconsin Deceptive Trade Practices Act
(Wis. Stat. Ann. §100.18, *et seq.*)
(Against Pfizer)

1197. Wisconsin Class Representative Wendy Quezaire incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1198. This cause of action is brought on behalf of the Wisconsin-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1199. Defendant is a "person, firm, corporation or association" within the meaning of Wis. Stat. Ann. §100.18(1).

1200. Plaintiff and the Class members are members of "the public" within the meaning of Wis. Stat. Ann. §100.18(1).

1201. The Ranitidine-Containing Products are "merchandise" within the meaning of Wis. Stat. Ann. §100.18(1).

1202. The Wisconsin Deceptive Trade Practices Act ("Wisconsin DTPA") prohibits any "assertion, representation or statement of fact which is untrue, deceptive or misleading." Wis. Stat. Ann. §100.18(1).

1203. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Wisconsin DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

1204. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Wisconsin DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts on the labels for its Ranitidine-Containing Products, including by printing expiration dates on its labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

1205. Defendant, directly or through its agents, employees, and/or subsidiaries, violated the Wisconsin DTPA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts in its marketing, advertising, and promotions for its Ranitidine-Containing Products, including that: such drugs were inherently defective, unreasonably dangerous, not fit to be used for their intended purpose, contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer.

1206. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding Ranitidine-Containing Products, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce, in violation of the Wisconsin DTPA.

1207. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

1208. Defendant's misrepresentations and omissions regarding the expiration dates of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

1209. Defendant's misrepresentations and omissions regarding package size, and resulting misrepresentations and omissions concerning appropriate length of ingestion, of Ranitidine-Containing Products were disseminated to Plaintiff and the Class members in a uniform manner.

1210. Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff and the Class members, about: (i) the inherently defective and unreasonably dangerous nature of Ranitidine-Containing Products; (ii) the safety of Ranitidine-Containing Products if used within the expiration dates; and (iii) the safety of Ranitidine-Containing Products when ingesting all doses contained within particular packaging.

1211. The facts regarding Ranitidine-Containing Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiff and the Class members, who consider such facts to be important to their purchase decisions with respect to Ranitidine-Containing Products.

1212. Plaintiff and the Class members were aggrieved by Defendant's violations of the Wisconsin DTPA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts as set forth above.

1213. Specifically, Plaintiff and the Class members were deceived by Defendant's misrepresentations, omissions, concealments, and failures to disclose material facts regarding Ranitidine-Containing Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiff and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

1214. Defendant's violations present a continuing risk to Plaintiff and the Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

1215. As a result of Defendant's violations of the Wisconsin DTPA, as alleged herein, Plaintiff and the Class members seek an order enjoining Defendant's unfair or deceptive acts or practices and awarding actual damages, costs, attorneys' fees, and any other just and proper relief available under the Wisconsin DTPA.

COUNT 70
Breach of Implied Warranty
(Wis. Stat. Ann. §402.314)
(Against Pfizer)

1216. Wisconsin Class Representative Wendy Quezaire incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1217. This cause of action is brought on behalf of the Wisconsin-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1218. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to the Wisconsin Class Representative and members of the Wisconsin Class and was in the business of selling such products.

1219. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1220. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1221. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

1222. Defendant had reason to know Plaintiff and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiff and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1223. Plaintiff and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1224. Plaintiff and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiff and each member of the Class, on the other hand.

1225. Further, Plaintiff and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

1226. Plaintiff and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiff and the members of the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1227. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiff and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 71
Unjust Enrichment
(Wisconsin Law)
(Against Pfizer)

1228. Wisconsin Class Representative Wendy Quezaire incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1229. This cause of action is brought on behalf of the Wisconsin-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1230. Plaintiff and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

1231. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiff and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. Accordingly, Plaintiff and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

1232. Defendant readily accepted and retained these benefits from Plaintiff and Class members and knowingly benefitted from its unjust conduct – at Plaintiff's and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

1233. It is unjust and inequitable for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiff and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

1234. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiff and Class members through its unjust and unlawful acts without paying for said benefits, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

1235. There is no express contract governing this dispute.

1236. Plaintiff and Class members do not have an adequate remedy at law.

27. Causes of Action on Behalf of the Wyoming-Pfizer Classes

COUNT 72
Breach of Implied Warranty
(Wyo. Stat. §34.1-2-314)
(Against Pfizer)

1237. Wyoming Class Representative Charles Longfield incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1238. This cause of action is brought on behalf of the Wyoming-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1239. At all relevant times, Defendant was a merchant with respect to Ranitidine-Containing Products which were sold to Wyoming Class Representatives and members of the Wyoming Class and was in the business of selling such products.

1240. Each Ranitidine-Containing Product sold by Defendant comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used, including impliedly warrantying on the labels for its Ranitidine-Containing Products that the products were safe and/or did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1241. Defendant breached its implied warranty of merchantability because its products cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1242. Defendant's Ranitidine-Containing Products are not fit for their intended use – or any use – because they have dangerous propensities when used as intended or within their expiration dates on the labels, and their use carries an increased risk of developing cancer.

1243. Defendant had reason to know Plaintiff and each member of the Class's particular purpose in buying Defendant's Ranitidine-Containing Products and knew that Plaintiff and each member of the Class relied on Defendant's skill or judgment in furnishing appropriate goods that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1244. Plaintiff and the Class did, in fact, rely on Defendant's skill and judgment in manufacturing Ranitidine-Containing Products that did not cause cancer or cause an unreasonable risk of cancer if used within the expiration dates on its labels.

1245. Plaintiff and each member of the Class have had sufficient direct dealings with either Defendant or its agents (including distributors, dealers, and authorized sellers) to establish privity of contract between Defendant, on the one hand, and Plaintiff and each member of the Class, on the other hand.

1246. Further, Plaintiff and each member of the Class were the intended third-party beneficiaries of the implied warranties made by Defendant to purchasers of its Ranitidine-Containing Products.

1247. Plaintiff and the members of the Class were injured as a direct and proximate result of Defendant's breaches of implied warranties of merchantability. Plaintiff and the members of

the Class were damaged as a result of Defendant's breaches of implied warranties of merchantability because, had they been aware of the unmerchantable condition of Ranitidine-Containing Products, they would not have purchased such drugs.

1248. As a result of Defendant's breaches of implied warranties of merchantability, as alleged herein, Plaintiff and the Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 73
Unjust Enrichment
(Wyoming Law)
(Against Pfizer)

1249. Wyoming Class Representative Charles Longfield incorporates the preceding allegations in paragraphs 2-3, 56-59, 60-85, 86-210, 232-251, and 262-289 as though fully set forth herein.

1250. This cause of action is brought on behalf of the Wyoming-Pfizer Class (for the purpose of this section, "Class") against Pfizer (for purposes of this Count only, "Defendant").

1251. Plaintiff and Class members conferred a benefit on Defendant in the form of payment of monies to purchase worthless Ranitidine-Containing Products or were otherwise in privity with Defendant through said transaction.

1252. In exchange for their payment of the purchase price of Defendant's Ranitidine-Containing Products, Plaintiff and Class members received the Ranitidine-Containing Products, which Defendant did not disclose contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed. ccordingly,

Plaintiff and Class members conferred a financial benefit on Defendant but did not receive their expected benefit therefrom.

1253. Defendant readily accepted, retained, and enjoyed these benefits from Plaintiff and Class members and knowingly benefitted from its unjust conduct – at Plaintiff's and the Class members' expense – by selling worthless Ranitidine-Containing Products that contained elevated levels of NDMA that rendered them unsafe and unfit for human consumption, and/or caused cancer, and that included expiration dates on the products' labels that exceeded the time period during which the products remained stable and, thus, resulting in higher, undisclosed, and unsafe levels of NDMA as time passed.

1254. Defendant knew that Plaintiff and Class members reasonably expected to receive safe and effective medications.

1255. It is unjust for the Defendant to retain these benefits because they were attained by misrepresenting and fraudulently concealing the true facts concerning the Ranitidine-Containing Products from Plaintiff and Class members, who would not have purchased the medications at all, but for the Defendant's misrepresentations and omissions.

1256. Equity cannot in good conscience permit Defendant to retain the benefits derived from Plaintiff and Class members through its unjust and unlawful acts without paying for said benefits, and, therefore, restitution or disgorgement of the amount of their unjust enrichment is required.

1257. Plaintiff and Class members do not have an adequate remedy at law, nor is there an express contract governing this dispute.

IX. PRAYER FOR RELIEF

Plaintiffs, on behalf of themselves and the proposed Classes, respectfully request that the Court:

A. Determine that this action may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23(a), (b)(2)-(3), and/or (c)(4), direct that reasonable notice of this action be given to the Classes, appoint Plaintiffs as named representatives of the Classes, and appoint Plaintiffs' counsel as Class Counsel;

B. Require Defendant to pay for sending notice to the certified Classes;

C. Enter judgment against Pfizer and in favor of Plaintiffs and the Classes;

D. Award damages (including actual, nominal, trebled, presumed, and statutory damages as provided by law) and restitution to the Classes in an amount to be determined at trial, plus pre- and post-judgment interest, in accordance with law;

E. Award punitive damages based on Pfizer's conduct,

F. Order disgorgement of Pfizer's profits;

G. Award reasonable attorneys' fees and costs; and,

H. For all such further relief as may be just and proper.

X. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs, on behalf of themselves and the Class(es), demand a trial by jury on all issues so triable.

Dated: January 24, 2022

Respectfully submitted,

/s/Melissa Ryan Clark
Melissa Ryan Clark
FEGAN SCOTT LLC
140 Broadway, 46th Fl.
New York, NY 10005
Ph: 347.353.1150
Fax: 312.264.0100
melissa@feganscott.com

FILED ON BEHALF OF:

Plaintiffs' Lead Counsel

Tracy A. Finken
Email: tfinken@anapolweiss.com
ANAPOL WEISS
One Logan Square
130 North 18th Street, Suite 1600
Philadelphia, PA 19103
Tel: (215) 735-1130

Robert C. Gilbert, FBN 561861
Email: gilbert@kolawyers.com
KOPELOWITZ OSTROW FERGUSON
WEISELBERG GILBERT
2800 Ponce de Leon Boulevard, Suite 1100
Coral Gables, FL 33134
Tel: (305) 384-7269

Michael L. McGlamry
Email: efile@pmkm.com
POPE McGLAMRY, P.C.
3391 Peachtree Road NE, Suite 300
Atlanta, GA 30326
Tel: (404) 523-7706

Adam Pulaski
Email: adam@pulaskilawfirm.com
PULASKI KHERKHER, PLLC
2925 Richmond Avenue, Suite 1725
Houston, TX 77098
Tel: (713) 664-4555

Plaintiffs' Co-Lead Counsel

Rosemarie Riddell Bogdan
Email: Rosemarie.bogdan@1800law1010.com
MARTIN, HARDING & MAZZOTTI
1222 Troy-Schenectady Road
PO Box 15141
Albany, NY 12212
Tel.: (518) 862-1200

Mark J. Dearman, FBN 0982407
Email: mdearman@rgrdlaw.com
ROBBINS GELLER RUDMAN & DOWD
120 East Palmetto Park Road, Suite 500
Boca Raton, FL 33432
Tel.: (561) 750-3000

Elizabeth A. Fegan
Email: beth@feganscott.com
FEGAN SCOTT, LLC
150 S. Wacker Dr., 24th Floor

Marlene J. Goldenberg
Email: mjgoldenberg@goldenberglaw.com
GOLDENBERG LAW, PLLC
800 LaSalle Avenue, Suite 2150
Minneapolis, MN 55402

Chicago, IL 60606
Tel.: (312) 741-1019

Ashley Keller
Email: ack@kellerlenkner.com
KELLER | LENKNER
150 N. Riverside Plaza, Suite 4270
Chicago, IL 60606
Tel.: (312) 741-5222

Roopal P. Luhana
Email: luhana@chaffinluhana.com
CHAFFIN LUHANA LLP
600 Third Avenue, 12th Floor
New York, NY 10016
Tel.: (888) 480-1123

Ricardo M. Martinez-Cid, FBN 383988
Email: RMartinez-Cid@Podhurst.com
PODHURST ORSECK, P.A.
SunTrust International Center
One S.E. 3rd Avenue, Suite 2300
Miami, FL 33130
Tel.: (305) 358-2800

Melanie H. Muhlstock
Email: mmuhlstock@yourlawyer.com
PARKER WAICHMAN LLP
6 Harbor Park DrivePort
Washington, NY 11050
Tel.: (516) 466-6500

Carmen S. Scott
Email: cscott@motleyrice.com
MOTLEY RICE LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
Tel.: (843) 216-9160

Sarah N. Westcot, FBN 1018272
Email: swestcot@bursor.com
BURSOR & FISHER, P.A.
Tel.: (612) 333-4662

Frederick Longer
Email: flonger@lfsblaw.com
LEVIN SEDRAN & BERMAN
510 Walnut Street, Suite 500
Philadelphia, PA 19106
Tel.: (215) 592-1500

Francisco R. Maderal, FBN 0041481
Email: frank@colson.com
COLSON HICKS EIDSON
255 Alhambra Circle, Penthouse
Coral Gables, FL 33134
Tel.: (305) 476-7400

Lauren S. Miller
Email: lmiller@corywatson.com
CORY WATSON, P.C.
2131 Magnolia Ave S
Birmingham, AL 35205
Tel.: (205) 328-2200

Daniel A. Nigh, FBN 30905
Email: dnigh@levinlaw.com
LEVIN PAPANTONIO THOMAS
MITCHELL RAFFERTY & PROCTOR, P.A.
316 South Baylen Street, Suite 600
Pensacola, FL 32502
Tel.: (888) 435-7001

Mikal C. Watts
Email: mcwatts@wattsguerra.com
WATTS GUERRA LLP
4 Dominion Drive
Building 3, Suite 100
San Antonio, TX 78257
Tel.: (800) 294-0055

Conlee S. Whiteley
Email: c.whiteley@kanner-law.com
KANNER & WHITELEY, L.L.C.

2665 S. Bayshore Drive, Suite 220
Miami, FL 33133
Tel.: (305) 330-5512

701 Camp Street
New Orleans, LA 70130
Tel.: (504) 524-5777

Frank Woodson
Email: Frank.Woodson@BeasleyAllen.com
BEASLEY ALLEN LAW FIRM
218 Commerce Street
Montgomery, AL 36104
Tel.: (334) 269-2343

R. Brent Wisner
Email: rbwisner@baumhedlundlaw.com
BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
Tel.: (310) 207-3233

Plaintiffs' Steering Committee
Plaintiffs' Law and Briefing Committee Co-Chairs
Plaintiffs' Liaison Counsel

Paige Boldt
Email: pboldt@wattsguerra.com
WATTS GUERRA LLP
5726 W. Hausman Rd., Ste. 119
San Antonio, TX 78249
Tel: (210) 447-0500

Je Yon Jung
Email: JJung@maylightfootlaw.com
MAY LIGHTFOOT, PLLC
3200 Martin Luther King Jr. Avenue S.E.
3rd Floor
Washington, DC 20032
Tel: (202) 918-1824

Adam W. Krause
Email: adam@krauseandkinsman.com
KRAUSE AND KINSMAN, LLC
4717 Grand Avenue, Suite 250
Kansas City, MO 64112
Tel: (816) 760-2700

Nicola Larmond-Harvey, FBN 0105312
Email: nicola@saunderslawyers.com
SAUNDERS & WALKER, P.A.
3491 Gandy Boulevard North, Suite 200
Pinellas Park, FL 33781
Tel: (727) 579-4500

Bradford B. Lear
Email: Lear@learwerts.com
LEAR WERTS LLP
103 Ripley Street
Columbia, MO 65203
Tel: (573) 875-1992

Plaintiffs' Leadership Development Committee